

---

**From:** Rohrbaugh, Mark (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=591AB6B2424B4B8997082718CBB29FAB-ROHRBAUM]  
**Sent:** 3/1/2018 4:00:27 PM  
**To:** NIH TDC Long [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1266a38ae3aa4208baa3753f5054395f-NIH TDC Lon]  
**Subject:** RE: KEI objecting to CAR T exclusive license, gets Congressional letter seeking compulsory licensing of Hep C drugs

FYI

Also note their attempt to get a Congressional petition (<https://www.keionline.org/26398>) to HHS for compulsory licensing of Hepatitis C treatments.

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From KEI:

## **KEI Appeals NIH/NCI Decision to Proceed with License of CD30 CAR T technology to Gilead/Kite (<https://www.keionline.org/26686>)**

Posted on February 27, 2018 by Andrew Goldman

KEI has appealed the NIH/NCI decision to proceed with the proposed exclusive license of anti-CD30 CAR T to Gilead, following an email of January 25, 2018 from Dr. David Lambertson of NCI rejecting all of KEI's substantive suggestions and objections.

KEI has asserted a right of appeal under 37 C.F.R. § 404.11(a)(3):

### **§ 404.11 Appeals.**

(a) In accordance with procedures prescribed by the Federal agency, the following parties may appeal to the agency head or designee any decision or determination concerning the grant, denial, modification, or termination of a license:

...

(3) A person who timely filed a written objection in response to the notice required by §404.7(a)(1)(i) or § 404.7(b)(1)(i) and who can demonstrate to the satisfaction of the Federal agency that such person may be damaged by the agency action.

KEI sent an email to Dr. Lambertson and NIH Director Francis Collins on February 14, 2018, informing NIH/NCI of our intent to appeal, requesting a copy of the procedures prescribed by the NIH for such appeals as none was available on the NIH website as of that date, and stating clearly that we would follow up with the actual document of our appeal detailing our arguments.

Minutes before KEI submitted the appeal document, Dr. Lambertson responded to my previous email to say:

Dear Mr. Goldman:

Thank you for your email of February 14, 2018.

As you noted, 37 CFR 404.11 (a)(3) permits an appeal for a person who can demonstrate to the satisfaction of the agency that such person may be damaged by the action.

We have considered your objection and determined that there is no likelihood that KEI will be damaged by the agency action. Accordingly, we will not entertain an appeal of our decision.

Best regards,  
David A. Lambertson, Ph.D.

A copy of Dr. Lambertson's email is [here](#).

We were surprised the NIH said it was refusing KEI a right to appeal prior to even seeing the appeal itself. We asked the NIH to reconsider the denial of our standing to file an appeal, and formally filed KEI's appeal with the NIH minutes later. The NIH seems to be arguing that taxpayers and patient advocates have no standing to challenge the grant of an exclusive license, regardless of which statutes the NIH may have ignored, or the errors in policy that are involved.

In the KEI appeal of the proposal for an exclusive license to Gilead/Kite, we articulate KEI's grounds for the appeal as a public interest organization that timely objected to the license and that represents taxpayers and patients, including cancer patients, who are likely to be damaged by an exclusive license of CAR T technology to Gilead without safeguards against excessive pricing or access barriers. We note the high prices of Novartis's Kymriah (\$475,000) and Gilead's Yescarta (\$373,000), the two CAR T products approved by the FDA in 2017.

### **NIH Arguments, and KEI Counterarguments**

The appeal iterates concerns raised in our initial objection while additionally refuting some of the points made by Dr. Lambertson on behalf of NCI, which included assertions that (1) an exclusive license would not create a monopoly, (2) the license had to proceed immediately, prior to the NIH having any results from the Phase 1 trial the NIH is currently funding, because NIH/NCI did not have the budget to conduct Phase 2 and 3 clinical trials, (3) that safeguards against excessive pricing and access barriers would not be included because they have not been used by NIH for years, and (4) certain regulations prevent the NIH from requiring transparency of R&D costs.

The KEI appeal made a variety of counterarguments, including:

- That it is useful to know the costs of clinical trials in order to evaluate the incentive needed to induce investments in Phase 2 or 3 trials, and that the NIH has refused to divulge its budget for the large Phase 1 clinical trial it is currently conducting.
- Clinical trials for CAR T treatments Kymriah and Yescarta both involved relatively small numbers of patients, less than 70 patients for one approval, and just over 100 for the other.
- The Bayh-Dole Act contains various provisions that the NIH seems to be ignoring, including the 35 USC § 209 requirement that NIH limit exclusivity to "what is reasonably necessary"; we cite, as an example, the case of the NIH licensing HIV drug ddI to Bristol-Myers Squibb, where the term of the license was shorter than the life of the patent and where the NIH exercised an option to make the license non-exclusive and enable competition before the patent expired in order to enhance the public health benefits of the invention. The NIH also capped the price that could be charged for ddI. In the case of the Gilead CD30 CAR T license, the NIH seems to be offering a life of patent license with no constraints on pricing at all, despite evidence of very high prices by Gilead for a CAR Treatment also licensed directly from the NIH.
- The regulations pointed to by Dr. Lambertson do not present a general barrier to requiring the disclosure of actual R&D outlays; KEI cites the example of extensive disclosures of post-licensing development activities as relating to the drug Fabrazyme.

### **40 U.S.C. § 559 Issues**

The appeal raises additional issues regarding the admitted refusal of NIH to adhere to 40 U.S.C. § 559, which requires that any federal agency disposing of federal property — including patents — must seek and obtain the antitrust advice of the Attorney General prior to the disposal to private interests. The statute is part of the



Federal Property and Administrative Services Act, which governs government procurement, utilization and disposal of property.

**40 U.S. Code § 559 – Advice of Attorney General with respect to antitrust law**

...

**(b) Advice Required.—**

**(1) In general.—**

An executive agency shall not dispose of property to a private interest until the agency has received the advice of the Attorney General on whether the disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law.

**(2) Exception.—This section does not apply to disposal of—**

**(A) real property, if the estimated fair market value is less than \$3,000,000; or**

**(B) personal property (other than a patent, process, technique, or invention), if the estimated fair market value is less than \$3,000,000.**

**(c) Notice to Attorney General.—**

**(1) In general.—**

An executive agency that contemplates disposing of property to a private interest shall promptly transmit notice of the proposed disposal, including probable terms and conditions, to the Attorney General.

**(2) Copy.—**Except for the General Services Administration, an executive agency that transmits notice under paragraph (1) shall simultaneously transmit a copy of the notice to the Administrator of General Services.

**(d) Advice From Attorney General.—**

Within a reasonable time, not later than 60 days, after receipt of notice under subsection (c), the Attorney General shall advise the Administrator and any interested executive agency whether, so far as the Attorney General can determine, the proposed disposition would tend to create or maintain a situation inconsistent with antitrust law.

**(e) Request for Information.—**On request from the Attorney General, the head of an executive agency shall furnish information the agency possesses that the Attorney General determines is appropriate or necessary to—

**(1) give advice required by this section; or**

**(2) determine whether any other disposition or proposed disposition of surplus property violates antitrust law.**

**(f) No Effect on Antitrust Law.—**

This subtitle does not impair, amend, or modify antitrust law or limit or prevent application of antitrust law to a person acquiring property under this subtitle.

We had sent an email to Karen Rogers, acting director of NIH Office of Technology Transfer, and David Lambertson on February 13, 2018 asking if NIH follows 40 U.S.C. § 559, also noting that 41 CFR 102-75.270 clarifies the double negative of the statute to clearly implicate patents:

**41 CFR 102-75.270 – Must antitrust laws be considered when disposing of property?**

Yes, antitrust laws must be considered in any case in which there is contemplated a disposal to any private interest of –

**(a) Real and related personal property that has an estimated fair market value of \$3 million or more; or**

**(b) Patents, processes, techniques, or inventions, irrespective of cost.**

Karen Rogers responded by claiming that the statute does not apply to NIH licensing practices:

When asked if she could direct us to authority that would support her position, she declined. As we noted in the appeal, the Bayh-Dole Act would seem to be compatible with and not override the FPASA:

35 U.S.C. § 209(a)(4) in fact creates an obligation that the licensing federal agency may only grant a license on a federally-owned invention if it, “will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws.” Logically, this suggests that the FPASA requirement applies; the NIH has abundant expertise in developing new medical technologies but does not have the antitrust expertise of the Attorney General.

[Access to Medicine](#), [Government Funded research](#), [Transparency CAR T](#), [David Lambertson](#), [Gilead](#), [Karen Rogers](#), [kite](#), [NIH](#)



**Andrew Goldman**

[More Posts](#)

## Post navigation

[FTC approves Celgene acquisition of Juno without requiring divestitures](#)

[WTO TRIPS Council \(February 2018\): South Africa’s statement on the regulatory review exception](#)

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**From:** Joe Allen [jallen@allen-assoc.com]  
**Sent:** 1/5/2017 8:38:46 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]  
**Subject:** Re: Letter to NY Times

I was referring to the general announcement. Did any other company apply?

On 1/5/2017 2:43 PM, Rohrbaugh, Mark (NIH/OD) [E] wrote:

> You mean the notice that we intended to grant Kite an exclusive license? As opposed to the general earlier announcement of the technology being available for licensing.

> No other company sent in a competing license application for the former. KEI objected

>

> -----Original Message-----

> From: Joe Allen [mailto:jallen@allen-assoc.com]

> Sent: Thursday, January 05, 2017 2:29 PM

> To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>

> Subject: Letter to NY Times

>

> Was thinking about our call and got an idea how to frame a letter to the editor. One more data point: did any other company besides Kite respond to the NIH notice that the patents were available for licensing?

 $\gamma$ 

> Thanks

 $\gamma$ 

> Sent from my iPhone

—

Joseph P. Allen  
President  
Allen and Associates  
60704 Rt. 26, South  
Bethesda, OH 43719  
(W) 740-484-1814  
(C) [REDACTED] b6  
www.allen-assoc.com

---

**From:** Joe Allen [jallen@allen-assoc.com]  
**Sent:** 12/22/2016 3:52:27 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]; Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]  
**Subject:** Jamie Love's comments to NIST

Just digging through my in box and wanted to be sure you'd seen  
this: <http://keionline.org/sites/default/files/KEI-9Dec2016-Bayh-Dole-NIST.pdf>

NIST was anticipating this so hopefully they will be dismissed as non-responsive to the notice.

--

Joseph P. Allen  
President  
Allen and Associates  
60704 Rt. 26, South  
Bethesda, OH 43719  
(W) 740-484-1814  
(c) b6  
[www.allen-assoc.com](http://www.allen-assoc.com)

---

**From:** Joe Allen [jallen@allen-assoc.com]  
**Sent:** 12/7/2017 3:03:20 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Hammersla, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87fb28aa23744c0b855ef0683ac2e8b4-hammerslaa]  
**Subject:** KEI Op-ed in the Hill urging HHS nominee Azar to march in to control drug prices

They never quit. Here's their latest:  
<http://thehill.com/opinion/healthcare/363322-american-taxpayers-will-be-alex-azar-s-shareholders-lets-hope-he-can-serve>

--

Joseph P. Allen  
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(C) b6  
[www.allen-assoc.com](http://www.allen-assoc.com)



**From:** Thalhammer-Reyero, Cristina (NIH/NHLBI) [E] [/O=NIH/OU=NIH/EXCHANGE/CN=OD/CN=THALHAMC]  
**Sent:** 1/9/2017 5:05:37 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/cn=OD/cn=ROHRBAUM]; Lambertson, David (NIH/NCI) [E] [/O=NIH/OU=NIH/EXCHANGE/cn=OD/cn=lambertsond]  
**CC:** Berkley, Dale (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/cn=OD/cn=BERKLEYD]; Chatterjee, Sabarni (NIH/NCI) [E] [/O=NIH/OU=NIH/EXCHANGE/cn=Recipients/cn=chatterjeesa]; Burke, Andy (NIH/NCI) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Burkear]  
**Subject:** RE: Prospective Grant of Exclusive Patent License: Development and Commercialization of Nitrite Salts for the Treatment, Amelioration, and Prevention by Any Route of Administration of Pulmonary Hypertension, Including All WHO Classifications of Pulmona...

Thank you Mark and Dave. Yes, I would like to have a consistent response, if there is already one.

Best regards,  
Cristina

---

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Monday, January 09, 2017 11:59 AM  
**To:** Lambertson, David (NIH/NCI) [E]  
**Cc:** Thalhammer-Reyero, Cristina (NIH/NHLBI) [E]; Berkley, Dale (NIH/OD) [E]; Chatterjee, Sabarni (NIH/NCI) [E]; Burke, Andy (NIH/NCI) [E]  
**Subject:** Re: Prospective Grant of Exclusive Patent License: Development and Commercialization of Nitrite Salts for the Treatment, Amelioration, and Prevention by Any Route of Administration of Pulmonary Hypertension, Including All WHO Classifications of Pulmona...

Some have responded, it would be good to have similar language. I can ask at the 2:00 TDC meeting

Sent from my iPhone

> On Jan 9, 2017, at 11:58 AM, Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov> wrote:

>

> Hi Cristina,

>

> I've not received this kind of a request from KEI.

b5

b5

Information if they have dealt with such a request.

>

> Cheers,

> Dave

>

> David A. Lambertson, Ph.D.

> Senior Licensing and Patenting Manager

> Technology Transfer Center

> National Cancer Institute/NIH

> david.lambertson@nih.gov

> http://ttc.nci.nih.gov/

>

> 9609 Medical Center Drive, Rm 1-E530 MSC 9702

> Bethesda, MD 20892-9702 (USPS)

> Rockville, MD 20850-9702 (Overnight/express mail)

> Phone (Main Office): 240-276-5530

> Phone (direct): (240) 276-6467

> Fax: 240-276-5504

>

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>

> -----Original Message-----

> **From:** Rohrbaugh, Mark (NIH/OD) [E]

> **Sent:** Monday, January 09, 2017 11:33 AM

> **To:** Thalhammer-Reyero, Cristina (NIH/NHLBI) [E] <cristina.thalhammer-reyero@nih.gov>; Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>

> **Cc:** Chatterjee, Sabarni (NIH/NCI) [E] <sabarni.chatterjee@nih.gov>; Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>; Burke, Andy (NIH/NCI) [E] <burkear@mail.nih.gov>

> **Subject:** RE: Prospective Grant of Exclusive Patent License: Development and Commercialization of Nitrite Salts for the Treatment, Amelioration, and Prevention by Any Route of Administration of Pulmonary Hypertension, Including All WHO Classifications of Pulmona...

REL0000023881

>  
> Other ICs have responded to this, I am copying Sabarni, Dave and Andy to see if they have a response to this question that they have used.  
>  
> -----Original Message-----  
> From: Thalhammer-Reyero, Cristina (NIH/NHLBI) [E]  
> Sent: Monday, January 09, 2017 11:30 AM  
> To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>  
> Subject: FW: Prospective Grant of Exclusive Patent License: Development and Commercialization of Nitrite Salts for the Treatment, Amelioration, and Prevention by Any Route of Administration of Pulmonary Hypertension, Including All WHO Classifications of Pulmona...  
>  
>  
> Good morning Mark and/or Dale.  
>  
> See below mail from James Love. Could you please suggest a response regarding providing "a copy of the analysis done to address the requirements of 35 USC 209(a) and 35 USC 209(f)"  
>  
> Thank you,  
> Cristina  
>  
> Cristina Thalhammer-Reyero, Ph.D., M.B.A.  
> Senior Licensing and Patenting Manager  
> 301-435-4507  
> ThalhamC@mail.nih.gov  
>  
>  
> This message may contain privileged and confidential information intended only for the use of the individual(s) or entity named above. If you are not the intended recipient, you are hereby notified that any use, dissemination, distribution, or copying of this message or its content is strictly prohibited. If you have received this message in error, please notify sender immediately and destroy the message without making a copy. Thank you.  
>  
> From: jamespackardlove@gmail.com [jamespackardlove@gmail.com] on behalf of Jamie Love [james.love@keionline.org]  
> Sent: Wednesday, January 04, 2017 10:55 AM  
> To: Thalhammer-Reyero, Cristina (NIH/NHLBI) [E]  
> Subject: Prospective Grant of Exclusive Patent License: Development and Commercialization of Nitrite Salts for the Treatment, Amelioration, and Prevention by Any Route of Administration of Pulmonary Hypertension, Including All WHO Classifications of Pulmonary H...  
>  
> Cristina  
>  
> Thalhammer-Reyero, Ph.D., MBA,  
> Senior Licensing and Patenting Manager,  
> NHLBI Office of Technology Transfer and Development  
>  
> Dear Dr.  
>  
> Thalhammer-Reyero,  
>  
> 1. Is there a CRADA associated with this license?  
> 2. May we have a copy of the analysis done to address the requirements of 35 USC 209(a) and 35 USC 209(f).  
>  
> James Love  
> Knowledge Ecology International  
>  
>  
>  
> -----  
>  
> James Love. Knowledge Ecology International <http://www.keionline.org/donate.html>  
> KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, [twitter.com/jamie\\_love](https://twitter.com/jamie_love)<[http://twitter.com/jamie\\_love](http://twitter.com/jamie_love)>

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**From:** Li, Chanel (NIH/OD) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D4BEEA214A074DCF8820DC28D0B70655-LIC17]  
**Sent:** 12/4/2017 3:42:58 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** Just when can NIH override a patent for a high-priced drug?

O

ver the past two years, the National Institutes of Health has been pressed by various lawmakers and advocacy groups to help alleviate the high cost of medicines. Citing federal law, they have urged the agency to take action when a prescription drug — one that was discovered with taxpayer dollars and later licensed to a drug maker — was not considered affordable. So far, though, the NIH has demurred.

On Thursday, NIH Director Francis Collins explained why. In testimony before a House Energy and Commerce subcommittee, he maintained federal law does not provide any “levers to pull.”

“If you look at the language of the (law), it really intends to cover a circumstance where a drug is simply not available to the public under any circumstances and then NIH is entitled to step in,” he said. “This is a little different. (A drug) is available, but at high cost. Our legal experts don’t feel that the law actually puts us in a position to step in.” (You can view his testimony [here](#) at the 1:20:45 mark).

But one group, which has worked closely with lawmakers to push the NIH, argued Collins got it wrong.

“What Collins did is tell a congressional committee that NIH doesn’t have authority to deal with excessive pricing — and that’s not true,” said Jamie Love, who heads Knowledge Ecology International. “I believe he misled the committee. The NIH has all sorts of leverage on the pricing problem.”

[https://www.statnews.com/pharmalot/2017/12/01/nih-director-patent-pricey-drug/?utm\\_campaign=rss](https://www.statnews.com/pharmalot/2017/12/01/nih-director-patent-pricey-drug/?utm_campaign=rss)



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**From:** Ahsan, Sidra (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E35C4D5FD1054799828811EBE4187A59-AHSANS]  
**Sent:** 7/10/2019 5:13:56 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: NIH's Response to KEI's Comments Regarding Exclusive License in STAT3 Inhibitor, GLG-302

Mark

**b5**

Best  
Sidra

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Tuesday, July 9, 2019 5:02 PM  
**To:** Ahsan, Sidra (NIH/NCI) [E] <sidra.ahsan@nih.gov>  
**Subject:** RE: NIH's Response to KEI's Comments Regarding Exclusive License in STAT3 Inhibitor, GLG-302

**b5**

**From:** Ahsan, Sidra (NIH/NCI) [E] <sidra.ahsan@nih.gov>  
**Sent:** Tuesday, July 9, 2019 4:30 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** FW: NIH's Response to KEI's Comments Regarding Exclusive License in STAT3 Inhibitor, GLG-302

Hi Mark

Please see email below. Richard asked me to consult with you regarding this.

**b5**

**b5**

Best  
Sidra

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Tuesday, July 9, 2019 3:05 PM  
**To:** Ahsan, Sidra (NIH/NCI) [E] <sidra.ahsan@nih.gov>  
**Cc:** James Love <james.love@keionline.org>  
**Subject:** NIH's Response to KEI's Comments Regarding Exclusive License in STAT3 Inhibitor, GLG-302

Dear Dr. Ahsan:

On June 19, 2019, you emailed James Love, Director of Knowledge Ecology International (KEI), in response to our comments regarding the "Prospective Grant of an Exclusive Patent License: The Development and Use of a Therapeutic STAT3 Inhibitor, GLG-302, in All Proliferative Diseases, Where STAT3 Is Present, to GLG Pharma LLC located in Jupiter, Florida, USA."

REL0000023883

A document attached to the email stated, in pertinent part: "We consider all comments prior to negotiating the proposed license. We will give your comments and suggestions serious consideration."

At 2:27 p.m. the same day, Mr. Love replied to your email and asked whether KEI will hear from NIH if it decides to proceed on the proposed license or accept or reject our suggestions. He also asked about the procedures for appealing under 37 C.F.R. § 404.11. You did not respond, and the link to the appeals procedure on NIH's website continues to be broken.

As soon as practicable, please clarify the following:

1. Does the document attached to your June 19, 2019 email constitute NIH's final decision regarding KEI's comments on the GLG-302 Stat 3 Inhibitor?; and
2. What are NIH's current appeal procedures and where they are disclosed to the public?

Thank you in advance for your consideration.

Sincerely,

--

Kathryn Ardizzone, Esq.  
Knowledge Economy International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

---

**From:** Myles, Renate (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/CN=RECIPIENTS/CN=MYLESR]  
**Sent:** 11/7/2016 2:28:50 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/cn=OD/cn=ROHRBAUM]; Fine, Amanda (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Fineab]  
**Subject:** RE: time sensitive request: talking points for today's xtandi meeting  
**Attachments:** Xtandi Reactive Statement\_Background Dft\_QA\_6.16.16.docx

Attached is the latest version of what have been using.

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Monday, November 07, 2016 9:27 AM  
**To:** Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@od.nih.gov>  
**Subject:** Fwd: time sensitive request: talking points for today's xtandi meeting

Do you have any talking points handy on the Xtandi march-in?

Sent from my iPhone

Begin forwarded message:

**From:** "Baker, Rebecca (NIH/OD) [E]" <bakerrg@od.nih.gov>  
**Date:** November 7, 2016 at 9:18:48 AM EST  
**To:** "Rohrbaugh, Mark (NIH/OD) [E]" <RohrBauM@OD.NIH.GOV>  
**Cc:** "Wolinetz, Carrie (NIH/OD) [E]" <carrie.wolinetz@nih.gov>  
**Subject:** time sensitive request: talking points for today's xtandi meeting

Hi Mark,

Update on today's meeting with KEI:  
Barb won't be joining and it will be just you, me, and Kathy.

**b5**

Thanks,  
Rebecca



## **Reactive Statement in Response to Xtandi March-In Request:**

The NIH considers use of its Bayh-Dole Act march-in authority very carefully. The authority can only be exercised if the agency determines, following an investigation, that one of four criteria is met. In the case of Xtandi (enzalutamide), the march-in request cited a failure by the contractor to take "effective steps to achieve practical application of the subject invention" and failure to satisfy "health and safety needs" as the criteria for march-in. Xtandi (enzalutamide) is broadly available as a prescription drug and NIH has no indication that the drug currently is or will be in short supply. Since the statutory criteria have not been met, NIH did not exercise its march-in authority on Xtandi (enzalutamide).

### Background on Bayh-Dole and march-in rights

The Bayh–Dole Act or University and Small Business Patent Procedures Act, adopted in 1980, is U.S. legislation that sets forth the rights and obligations of the government and federal funding recipients to inventions that result from federal government-funded research. Among other things, it gives a grantee or a contractor (i.e. U.S. universities, businesses, and non-profits) the right to assert ownership on the inventions it makes with federal funding, but requires the grantee or contractor to make reasonable efforts to commercialize and achieve practical application that the invention is being used and that its benefits are available to the public on reasonable terms.

### Background on requests for march-in rights

When a federal agency receives or identifies information on what might warrant the exercise of its march-in rights, it reviews the public information available on the question that has been raised and, if necessary, requests information from the owner of the invention. Depending on the specific facts and circumstances that are being reviewed and the information identified during the review, the government's march-in right allows the funding agency to conduct an administrative proceeding. If it finds that one of the four statutory criteria is met, it can grant additional licenses to other "reasonable applicants." This authority can only be exercised if the agency makes such a determination. The most common of these considerations are failure by the contractor to take "effective steps to achieve practical application of the subject invention" or a failure to satisfy "health and safety needs".

### QA:

#### **Why isn't NIH using its march-in rights to control drug pricing?**

The Bayh-Dole Act was created to encourage the commercialization of inventions made with government funding. For a government agency to exercise its Bayh-Dole march-in authority, certain criteria must be met. The most common of these are a failure by the contractor to take "effective steps to achieve practical application of the subject invention" (for example, if a company has rights to the patent for a drug, but is not taking reasonable effort to bring it to market) or failure to satisfy "health and safety needs" of consumers (for example, the drug is in short supply and consumers cannot obtain the drug).

#### **If the price is very high, doesn't that limit access for patients?**

Xtandi is similar to most new generations of drugs. Access is determined by healthcare coverage. Additionally, Astellas Pharma Inc. (the company that produces Xtandi) has a program that provides the drug at reduced cost for those who are eligible. The NIH agrees with earlier public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling prices.

#### **Has a march-in petition ever been granted by NIH?**

To date, no federal agency has exercised its march-in rights. NIH has considered the use of march-in on several occasions and either worked with parties involved (company and petitioner) to reach an

agreement to address the issues raised, such was the case with CellPro, or worked with the company until the matter was resolved, such was the case with Fabrazyme. See march-in responses at [www.ott.nih.gov/policies-reports](http://www.ott.nih.gov/policies-reports). NIH does not require a petition to use its march-in authority.

**What did NIH fund in the development of Xtandi?**

NIH funded the basic research in the development of Xtandi. Astellas provided additional support and resources to commercialize the product. Xtandi is manufactured by Medivation in the United States.

---

**From:** Surabian, Karen (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=604A0E2013504631921434A90B327010-SURABIANK\_1]  
**Sent:** 7/2/2018 7:05:26 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Frisbie, Suzanne (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c402740ceaad4d4f97a8c28f16fbb349-frisbies]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]; Kirby, Tara (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2368a591fa4c4932a802e5d467fb49ed-tarak]; Sayyid, Fatima (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b9e45041bdb43719f7113a5aae27057-sayyidf]  
**Subject:** FW: KEI comments on Prospective Grant of Exclusive Patent Commercialization License: Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and Infection to The University of Liverpool, located in Liverpool, UK  
**Attachments:** KEI-NIH-Comments-Streptococcus-Pneumonia-Liverpool-2Jul2018 .pdf; Draft Email Response 070218 updated.docx

Hello Mark,

Does the following email and attached from KEI change the response (draft attached), other than updating and adding in today's date in the first sentence.

Thank you.

Sincerely,

Karen

---

Karen T. Surabian  
Licensing and Patenting Manager  
CDC Team  
Technology Transfer and Intellectual Property Office (TTIPO)  
National Institute of Allergy and Infectious Diseases (NIAID)  
National Institutes of Health (NIH)  
5601 Fishers Lane, Rm. 2G48, MSC 9804  
Rockville, MD 20892

Phone: [+1-301-594-9719](tel:+1-301-594-9719)  
Email: [karen.surabian@nih.gov](mailto:karen.surabian@nih.gov)

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**From:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>  
**Sent:** Monday, July 2, 2018 2:52 PM  
**To:** Surabian, Karen (NIH/NIAID) [E] <[karen.surabian@nih.gov](mailto:karen.surabian@nih.gov)>  
**Cc:** Luis Gil Abinader <[luis.gil.abinader@keionline.org](mailto:luis.gil.abinader@keionline.org)>; Claire Cassedy <[claire.cassedy@keionline.org](mailto:claire.cassedy@keionline.org)>

REL0000023885



**Subject:** KEI comments on Prospective Grant of Exclusive Patent Commercialization License: Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and Infection to The University of Liverpool, located in Liverpool, UK

--

James Love. Knowledge Ecology International

<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, [twitter.com/jamie\\_love](https://twitter.com/jamie_love)

July 2, 2018

Karen Surabian  
Licensing and Patenting Manager  
Technology Transfer and Intellectual Property Office  
National Institute of Allergy and Infectious Diseases  
[karen.surabian@nih.gov](mailto:karen.surabian@nih.gov).

Re: Prospective Grant of Exclusive Patent Commercialization License:  
Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and  
Infection to The University of Liverpool, located in Liverpool, UK

Dear Karen Surabian,

These are the KEI comments relating the proposed exclusive license to inventions identified in the federal notice 83 FR 28002.

1. The license should prohibit the licensee from charging more for any drug, vaccine, medical device or any other health technology using the invention than the median price charged in the seven countries with the largest gross domestic product (GDP), that also have a per capita income of at least 50 percent of the United States, as measured by the World Bank Atlas Method.
2. The license should not be exclusive in any country with a per capita income less than 30 percent of the United States per capita income, as measured by the World Bank Atlas method.
3. The license should include an obligation to make an annual report to the NIH that would be available to the public on the research and development (R&D) costs associated with the development of any product that uses the invention, including reporting separately and individually the outlays on each clinical trial. This type of information should be made available to the public in order to ensure that the terms of the licenses over NIH-owned inventions can be evaluated, in light of the requirements of 35 USC 209. Indeed, the most relevant information regarding 35 USC 209 is that the expected costs of bringing an invention to practical application, and the data collected from license holders, is important evidence and should be available and considered.
4. To guarantee that the scope of the license is sufficiently narrow, as required under 35 USC 209, the exclusivity of the license in the United States should be reduced by one year for every \$500 million in revenue equivalents, earned after the first \$1 billion, where revenue equivalent is defined as global cumulative

sales, plus market entry rewards plus government grants or tax credits, for the product or products using the invention.

The Federal Register notice would have been more informative if we knew more about the extent of NIH or other government agency funding in this area, and also if there are plans for the NIH, BARDA or any other U.S. government agency to continue to support the development of products based upon this invention. We do note that 32 administering institutes or other government agencies that report grants in the NIH RePORT database have funded more than \$1 billion in research grants for streptococcus pneumonia or streptococcus pneumoniae.

Sincerely



Luis Gil Abinader  
Knowledge Ecology International  
luis.gil.abinader@keionline.org

#### Annex: Government funding of research in NIH RePORT database

(Funding data available only for NIH, CDC, FDA, and ACF)

**July 2, 2018 Text Search:** "streptococcus pneumonia" "streptococcus pneumoniae" (or), **Search in:** Projects **Admin IC:** All, **Fiscal Year:** All Fiscal Years

Administering Agency	projects	Project funding	sub projects	Sub Project funding
NIAID	1,569	\$589,508,807	104	\$43,190,320
NIGMS	265	\$102,398,204	25	\$3,488,408
NHLBI	234	\$86,247,316	55	\$17,791,985
NIDCD	205	\$68,803,279	12	\$1,439,957
NIA	101	\$21,227,109	6	\$975,142
NIDCR	75	\$20,234,993	5	\$782,428
NICHD	67	\$27,311,146	17	
NEI	58	\$18,749,443		
FDA	56			
NIAAA	40	\$8,062,504	26	\$4,259,685
NIEHS	31	\$11,977,092	17	\$5,018,550
VA	29			

FIC	26	\$3,949,321		
NCI	26	\$6,875,593	6	\$4,763,834
NIDA	22	\$4,787,617		
NINDS	19	\$5,108,633	4	
AHRQ	19			
NIAMS	17	\$6,115,167	5	\$403,020
NIMH	17	\$3,290,727		
NIDDK	15	\$3,824,942	1	\$147,712
CID	14	\$14,828,991		
NIMHD	11	\$3,471,409	3	\$1,029,828
NIBIB	7	\$1,447,386		
NCRR	6	\$4,445,858	112	\$3,336,220
NCIRD	6	\$3,934,512		
NHGRI	4	\$1,855,111	1	\$233,333
OD	4	\$2,938,501		
NCCIH	4	\$1,200,391		
CLC	3			
CIT	2			
NIADDK	1	\$162,792		
ODCDC			3	\$650,465
Totals	2,953	\$1,022,756,844	402	\$87,510,887



**b5**

---

**From:** Collins, Francis (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=COLLINSFR]  
**Sent:** 6/8/2016 12:14:37 AM  
**To:** Hudson, Kathy (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Hudsonk]; Tabak, Lawrence (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=nidcr/cn=tabakl]; Wolinetz, Carrie (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Wolinetzcdc9a]; Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]; McGarey, Barbara (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=MCGAREYB]  
**Subject:** FW: Use Bayh Dole to Lower Drug Prices  
**Attachments:** Nature Medicine FINAL.pdf

FYI

---

**From:** Alfred Engelberg [mailto:[aengelberg@nglbrg.com](mailto:aengelberg@nglbrg.com)]  
**Sent:** Tuesday, June 07, 2016 6:23 PM  
**To:** Alfred Engelberg  
**Subject:** Use Bayh Dole to Lower Drug Prices

I thought you would be interested in this Opinion piece that was published in Nature Medicine online today.

*Alfred Engelberg*  
[aengelberg@nglbrg.com](mailto:aengelberg@nglbrg.com)

# Use the Bayh-Dole Act to lower drug prices for government healthcare programs

Alfred B Engelberg & Aaron S Kesselheim

**As drug prices have increased, there is also greater pressure to find ways to ensure access to medicines. The US government may be able to lower drug costs for federal programs such as Medicare and Medicaid through existing law.**

The Bayh-Dole Act of 1980 permits the ownership of patents resulting from federally-funded research to remain with the inventors and their employers. Government research grantees and their institutions now earn billions from royalties and equity interests that result from the sale or exclusive licensing of these patents.<sup>1</sup> In recent years, controversy has arisen when drugs covered by these patents have been sold at excessively high prices, since taxpayers have already contributed to the drugs' discovery, as part of the more than \$30 billion annually the US government spends on biomedical research.

In discussing ways to reduce drug costs, legislators and public-health advocates have largely overlooked a provision in the Bayh-Dole Act that could help. Section 202 requires research grantees that obtain patents claiming federally-funded inventions to confer a nonexclusive, royalty-free license back to the US government, which permits the government to practice the invention or to have it practiced on the government's behalf. When advocating for the enactment of the Bayh-Dole Act, former Senator Birch Bayh (D-IN) stated that this license allows the government to "use for itself and the public good inventions arising out of research that the Federal Government helps to support."<sup>2</sup> This use could include that for government healthcare programs such as Medicare and Medicaid.

To our knowledge, the government has never exercised its right to have a prescription drug manufactured on its behalf. One reason may be that, although many drugs have their origins in federally-funded research, pharmaceutical companies obtain other patents covering these drugs during their development into FDA-approved products. The government's license does not extend to such privately-funded patents, which limits the situations in which the government could use its license.

Still, Section 202 could be useful in some cases. Earlier this year, two consumer-interest organizations, Knowledge Ecology International and Union for Affordable Cancer Treatment, filed a petition requesting the government to use Section 202 to authorize the production of a generic version of the prostate cancer drug enzalutamide (Xtandi), because the drug's list price in the US is two to three times higher than it is in Europe and Australia. All patents currently registered with the US Food and Drug Administration (FDA) covering enzalutamide are licensed to the US government under Section 202. As this article went to press, the US Department of Health and Human Services had not yet ruled on the petition. But the government has received an offer from a generic manufacturer to supply enzalutamide for government programs at \$3 per pill, as compared to the \$42.38 per pill the government now pays—a potential annual savings of over \$57,000 per patient.

A potential obstacle to the exercise of the government's Section 202 license is the patent certification requirements of the Hatch-Waxman Act of 1984. Hatch-Waxman requires a manufacturer that is seeking approval to sell a generic copy of a patented new drug like enzalutamide to certify that any patents on the new drug are invalid or will not be infringed. This requirement may seem to prevent a

generic manufacturer that has no basis for substantively challenging enzalutamide's patents from obtaining FDA approval before the patents expire. But because of the government's Section 202 license, we believe that a generic manufacturer could certify that the patents will not be infringed because approval is being sought for the sole purpose of producing enzalutamide for sale to the government.

Any suit claiming infringement of the enzalutamide patents despite such a certification should be dismissed by a federal court, because the law<sup>3</sup> prohibits the court from interfering with the right of a government

supplier to bid on or participate in the sale of products to the government, irrespective of the existence of patents.<sup>4</sup> The only available course of action for acts of patent infringement by or for the government is to initiate a suit in the US Court of Federal Claims—but the Section 202 license would provide the government with a complete defense. In addition to its patents, enzalutamide is protected under Hatch-Waxman by a five-year exclusivity for new chemical entities that expires on 31 August 2017, but an application for generic approval containing a certification of non-infringement may be filed 1 year before the exclusivity expires. There are other drugs,

such as the anti-HIV medication emtricitabine (Emtriva), subject to a Section 202 license for which a similar patent certification could be filed immediately.

Some will argue that by exercising its license, the government would undermine the value of commercial rights and adversely affect the willingness of the pharmaceutical industry to invest in the commercialization of federally funded research discoveries. But many manufacturers have reduced their investment in internal drug discovery research and become increasingly dependent on licensing ideas emerging from public funding. There is no reason to believe that they will abandon their essential relationship with academia simply because profits are reduced somewhat by the operation of the Section 202 license.

The economic benefits that result from federally-funded biomedical research should be more equitably shared with the public, and the section 202 license can help accomplish that goal for certain drugs. In the long run, Congress should consider ways to amend the Bayh-Dole Act to achieve this outcome more broadly. Until then, the government should utilize its Section 202 license to achieve lower drug prices for public programs whenever possible.

*Alfred B. Engelberg is a trustee at the Engelberg Foundation in Palm Beach, Florida, and Aaron S. Kesselheim is an associate professor of medicine at the Brigham and Women's Hospital and Harvard Medical School in Boston.*

**"The economic benefits that result from federally-funded biomedical research should be more equitably shared with the public."**

1. Watanabe, T. UCLA will get hundreds of millions for rights to prostate cancer drug. *LA Times* (4 March 2016).
2. [http://bayhdolecentral.com/JoeAllen\\_part3/statment.on.s.414.pdf](http://bayhdolecentral.com/JoeAllen_part3/statment.on.s.414.pdf).
3. 28 U.S.C. § 1498(a) (2015).
4. *Gore v. Garlock*, 842 F.2d 1275, 1282 (Fed. Cir. 1988).

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**From:** Koniges, Ursula (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D5AE2C3139654BC0B9B95718D516310B-KONIGESUM]  
**Sent:** 1/31/2019 7:10:25 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Plank-Bazinet, Jennifer (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a7faf0b33bb4b90b07b212e49ec08e3-plankjl\_f24]; Fennington, Kelly (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e2d306aa244429b0f51d365bd24a26-fenningk]  
**Subject:** Drug Pricing BRAIN Record – Ursula Has Uploaded Into BRAIN  
**Attachments:** Drug Pricing (changes highlighted)\_LJ.docx

Hi Mark,

Just a quick FYI to loop you into where the Drug Pricing record is in the BRAIN review process. **I've uploaded the Lyric-reviewed Drug Pricing record into BRAIN for us**, so we're done with that.

Rationale: Jennifer and Kelly recommended that, due to time concerns, we should upload the Lyric-reviewed Drug Pricing brief into BRAIN ASAP, even though we're still waiting on comments from Carrie.

Follow-up Needed:

- If Carrie ends up recommending edits, I'll be happy to assist with incorporating those into the record later.
- Lyric had one question embedded in her review –

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b5

Thanks,  
-Ursula

**b5**



**b5**

**b5**

**b5**

**b5**

---

**From:** Joe Allen [jallen@allen-assoc.com]  
**Sent:** 7/23/2017 12:55:02 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Hammersla, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87fb28aa23744c0b855ef0683ac2e8b4-hammerslaa]  
**Subject:** Experts Push Expanded March In Rights As Way to Bring Down Prices  
**Attachments:** Jamie Love and Henry Waxman call for expanding B-D march in rights.docx

See attachment. The "experts" are Jamie Love and former Rep Henry Waxman.

<https://insidehealthpolicy.com/daily-news/experts-push-expanded-%E2%80%98march-rights%E2%80%99-way-bring-down-prices>

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*At FDA public meeting on Hatch-Waxman law and drug prices . . .*

## Experts Push Expanded 'March-In Rights' As Way To Bring Down Prices

July 21, 2017

During an all-day public meeting on the Hatch-Waxman drug patent law and how FDA could help bring down drug prices by speeding generics to market, one presenter raised the idea of expanding the Bayh-Dole Act's march-in rights to cover any product regulated by FDA as a way to rein in prices -- an idea the agency noted "would be of interest."

Meeting presenters -- including academics and researchers, generic drug makers, pharmaceutical industry groups, payers and patient representatives -- also discussed during the Tuesday (July 18) meeting a need for FDA to use its authority to waive requirements for shared Risk Evaluation and Mitigation Strategies (REMS) between branded and generic drug firms. Some presenters called for FDA to increase transparency around the citizen petition process and other tactics used by brand drug makers to delay generics from entering the market.

**James Love, director of Knowledge Ecology International, told the FDA panel "there should be more robust authority in the United States for a non-voluntary licensing of patents."** When asked by FDA's Grail Sipes, director of the Office of Regulatory Policy, what compulsory licensing rules should be amended to grant FDA more authority, Love called for expanding Bayh-Dole march-in rights to "any drug, vaccine or medical device that's regulated by the FDA."

Under the Bayh-Dole Act, if a federal agency helps fund an invention, it may exercise "march-in rights," requiring the patent holder to "grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances." If the patent holder refuses to grant the license, the federal agency may "grant such a license itself," the law states.

FDA expressed interest, asking Love to further expand on his idea in comments for the docket. "If you have any further thoughts on these issues, particularly authority for expanding march-in rights, that would be of interest," Sipes said.

**In comments submitted to FDA's meeting docket, former House Democrat and Hatch-Waxman author, Henry Waxman, also advocated using the Bayh-Dole Act to regulate drug prices.** "Use the current authority in the Bayh-Dole Act, or amend the act's provisions, to establish allowable constraints on the prices that manufacturers can charge or require manufacturers to enter into a contract for government manufacturing ... When prices are unreasonable, the federal government could use Bayh-Dole provisions to manufacture the drug or have it manufactured on the government's behalf," wrote Waxman, currently chairman of Waxman Strategies.

Although Steven Knievel, organizer for Public Citizen's Access to Medicines Program, also brought up use of march-in rights in the case of U.S. government-funded biomedical inventions, he noted the law is currently limited to those products.

"We believe those [march-in] rights are limited to government-funded inventions .... we would be very interested in that law being expanded to include funding for more stages of development, but that is my understanding of the statute," Knievel said.

Up to now, the National Institutes of Health has rejected pressure to use its march-in authority under the Bayh-Dole Act to provide more affordable products to patients. In 2013 the agency stated that march-in authority "is not an appropriate means of controlling prices of drugs broadly available to physicians and patients" and that it "is not appropriate to assess the price of one drug out of the context of a country's entire health care delivery and drug pricing/reimbursement system."

More recently, in April lawmakers urged President Donald Trump to direct NIH to issue public guidance on when it will invoke its march-in rights. -- **Beth Wang** ([bwang@iwonews.com](mailto:bwang@iwonews.com))

Related News | Drug Pricing | Rx Drugs |  
98489

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**From:** Vepa, Sury (NIH/NCATS) [E] [/O=NIH/OU=EXTERNAL (FYDIBOHF25SPDLT)/CN=RECIPIENTS/CN=CE576258D4054767B9B2279A8FCD32E4]  
**Sent:** 5/31/2017 8:50:23 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/NCATS/cn=OD/cn=ROHRBAUM]; Lambertson, David (NIH/NCI) [E] [/O=NIH/OU=EXTERNAL (FYDIBOHF25SPDLT)/cn=Recipients/cn=d3b89ec7d5204c939ea3524c71ad4098]  
**Subject:** RE: Prospective Grant of Exclusive Patent License: Mutant IDH1 Inhibitors

Thanks. I will work with this as the proposed response and if more information is needed, will get in touch with you.

I was told by Donna that there is a website which makes available the notices prepublication.

Sury Vepa  
301-217-9197  
[b6] cell)

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**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Wednesday, May 31, 2017 4:47 PM  
**To:** Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>; Vepa, Sury (NIH/NCATS) [E] <sury.vepa@nih.gov>  
**Subject:** RE: Prospective Grant of Exclusive Patent License: Mutant IDH1 Inhibitors

Looks good to me.

They became aware of another FR notice before it was published. Not sure if they get them on line first.

**From:** Lambertson, David (NIH/NCI) [E]  
**Sent:** Wednesday, May 31, 2017 4:44 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Vepa, Sury (NIH/NCATS) [E] <sury.vepa@nih.gov>  
**Subject:** RE: Prospective Grant of Exclusive Patent License: Mutant IDH1 Inhibitors

b5

David A. Lambertson, Ph.D.  
Senior Technology Transfer Manager  
Technology Transfer Center  
National Cancer Institute/NIH  
[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)  
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REL0000023893



9609 Medical Center Drive, Rm 1-E530 MSC 9702  
Bethesda, MD 20892-9702 (USPS)  
Rockville, MD 20850-9702 (Overnight/express mail)  
Phone (Main Office): 240-276-5530  
Phone (direct): (240) 276-6467  
Fax: 240-276-5504

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**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Wednesday, May 31, 2017 4:39 PM  
**To:** Vepa, Sury (NIH/NCATS) [E] <[sury.vepa@nih.gov](mailto:sury.vepa@nih.gov)>; Lambertson, David (NIH/NCI) [E] <[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)>  
**Subject:** RE: Prospective Grant of Exclusive Patent License: Mutant IDH1 Inhibitors

**b5**

**From:** Vepa, Sury (NIH/NCATS) [E]  
**Sent:** Wednesday, May 31, 2017 4:01 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[RohrBauM@OD.NIH.GOV](mailto:RohrBauM@OD.NIH.GOV)>; Lambertson, David (NIH/NCI) [E] <[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)>  
**Subject:** FW: Prospective Grant of Exclusive Patent License: Mutant IDH1 Inhibitors

Hi Mark,

In response to recent NCATS FR Notice of Intent to Grant an Exclusive License to GeneXion, Inc. for IDH1 technology (briefed ELCG a couple of weeks ago), I received the email below from KEI. I discussed this with Lili and we wanted to have your advice on before we formulate a response to this.

Please let me know if you want to discuss this further.

Dave,

I am sending this to you as general information and to share this with NIH TT community at an appropriate time.

Thanks,

Sury

Sury Vepa  
301-217-9197  
(b6) cell)

REL0000023893

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**From:** jamespackardlove@gmail.com [mailto:jamespackardlove@gmail.com] **On Behalf Of** Jamie Love  
**Sent:** Wednesday, May 31, 2017 12:43 PM  
**To:** Vepa, Sury (NIH/NCATS) [E] <sury.vepa@nih.gov>  
**Cc:** Diane Singhroy <diane.singhroy@keionline.org>; Claire Cassedy <claire.cassedy@keionline.org>; Manon Ress <manon.ress@keionline.org>; Andrew S. Goldman <andrew.goldman@keionline.org>  
**Subject:** Prospective Grant of Exclusive Patent License: Mutant IDH1 Inhibitors

Sury Vepa, Ph.D., J.D.,  
Senior Licensing and Patenting Manager  
National Center for Advancing Translational Sciences'  
NIH, 9800 Medical Center Drive, Rockville, MD 20850,  
Phone: 301-217-9197,  
Fax: 301-217-5736,  
email [sury.vepa@nih.gov](mailto:sury.vepa@nih.gov).

Dear Dr. Vepa,

1. We propose there be language in the license to ensure that prices for products are "reasonable" -- the standard in 35 U.S.C. § 201(f) -- and do not discriminate against U.S. residents.

One very basic protection for US. residents is to ensure that prices are not higher than the median price of other high income industrialized countries.

For example, the license could say:

The [agency] will normally expect the licensee to make products available to the public in the United States at prices no higher than the median price charged in the seven countries with the largest GDP, that have per capita incomes of at least half that of the United States.

We may propose additional pricing safeguards later, including to address access in developing countries.

2. We would like to learn more about the technology being licensed. Could we set up a call with myself, Diane Singhroy and persons at the NIH who can answer questions about the technology and the NIH role in its funding?

James Love  
KEI

--

James Love. Knowledge Ecology International

<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,

[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

REL0000023893

---

**From:** Berkson, Laura (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ADB561AB47E54FDC94E2A54682514434-BERKSONLD]  
**Sent:** 12/1/2017 4:46:18 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: BRAIN brief on Pricing

**b5**

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Friday, December 01, 2017 11:42 AM  
**To:** Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>  
**Subject:** BRAIN brief on Pricing

**b5**

Thanks

Mark L. Rohrbaugh, Ph.D., J.D.  
Special Advisor for Technology Transfer  
Director, Division of Technology Transfer and Innovation Policy  
Office of Science Policy  
Office of the Director  
National Institutes of Health

**From:** Berkley, Dale (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=BERKLEYD]  
**Sent:** 1/9/2017 5:05:32 PM  
**To:** Thalhammer-Reyero, Cristina (NIH/NHLBI) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=THALHAMC]; Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]  
**Subject:** RE: Prospective Grant of Exclusive Patent License: Development and Commercialization of Nitrite Salts for the Treatment, Amelioration, and Prevention by Any Route of Administration of Pulmonary Hypertension, Including All WHO Classifications of Pulmona...

b5

Best, Dale

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
301-496-6043  
301-402-2528(Fax)

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-----Original Message-----

**From:** Thalhammer-Reyero, Cristina (NIH/NHLBI) [E]  
**Sent:** Monday, January 09, 2017 11:30 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>  
**Subject:** FW: Prospective Grant of Exclusive Patent License: Development and Commercialization of Nitrite Salts for the Treatment, Amelioration, and Prevention by Any Route of Administration of Pulmonary Hypertension, Including All WHO Classifications of Pulmona...

Good morning Mark and/or Dale.

See below mail from James Love. Could you please suggest a response regarding providing "a copy of the analysis done to address the requirements of 35 USC 209(a) and 35 USC 209(f)"

Thank you,  
Cristina

Cristina Thalhammer-Reyero, Ph.D., M.B.A.  
Senior Licensing and Patenting Manager  
301-435-4507  
ThalhamC@mail.nih.gov

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**From:** jamespackardlove@gmail.com [jamespackardlove@gmail.com] on behalf of Jamie Love [james.love@keionline.org]  
**Sent:** Wednesday, January 04, 2017 10:55 AM  
**To:** Thalhammer-Reyero, Cristina (NIH/NHLBI) [E]  
**Subject:** Prospective Grant of Exclusive Patent License: Development and Commercialization of Nitrite Salts for the Treatment, Amelioration, and Prevention by Any Route of Administration of Pulmonary Hypertension, Including All WHO Classifications of Pulmonary H...

Cristina

Thalhammer-Reyero, Ph.D., MBA,  
Senior Licensing and Patenting Manager,  
NHLBI Office of Technology Transfer and Development

Dear Dr.

Thalhammer-Reyero,

1. Is there a CRADA associated with this license?

REL0000023895

2. May we have a copy of the analysis done to address the requirements of 35 USC 209(a) and 35 USC 209(f).

James Love  
Knowledge Ecology International

-----

James Love. Knowledge Ecology International <http://www.keionline.org/donate.html>  
KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,  
[twitter.com/jamie\\_love](http://twitter.com/jamie_love)<[http://twitter.com/jamie\\_love](http://twitter.com/jamie_love)>

---

**From:** Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]  
**Sent:** 7/2/2018 8:04:08 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]  
**CC:** Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodgrir]  
**Subject:** Draft KEI Response  
**Attachments:** A-301-2018\_Response to KEI.docx

Good afternoon Mark and Dale,

I attach a draft response to KEI, who has objected to a recent Notice of Intent to Grant an exclusive license, for your review and consideration. Please let me know if you think the response is acceptable or if you would suggest changes before the response is sent. If you need anything else, let me know.

Thanks,  
Dave

David A. Lambertson, Ph.D.  
Senior Technology Transfer Manager  
Technology Transfer Center  
National Cancer Institute/NIH  
[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)  
<http://ttc.nci.nih.gov/>

9609 Medical Center Drive, Rm 1-E530 MSC 9702  
Bethesda, MD 20892-9702 (USPS)  
Rockville, MD 20850-9702 (Overnight/express mail)  
Phone (Main Office): 240-276-5530  
Phone (direct): (240) 276-6467  
Fax: 240-276-5504

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**b5**



**b5**

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**From:** Rodriguez, Richard (NIH/NCI) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=RODRIQUR]  
**Sent:** 5/10/2016 1:03:30 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]  
**Subject:** FW: Prospective Grant of Exclusive License: Development of 5T4 Antibodies in Human Cancer Therapeutics and Diagnostics to Ovensa, Inc. ("Ovensa") located in Ontario, Canada.

FYI and please let me know when we can discuss.

Thanks,

Richard

---

**From:** Freel, Rose (NIH/NCI) [E]  
**Sent:** Monday, May 09, 2016 4:08 PM  
**To:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
**Subject:** FW: Prospective Grant of Exclusive License: Development of 5T4 Antibodies in Human Cancer Therapeutics and Diagnostics to Ovensa, Inc. ("Ovensa") located in Ontario, Canada.

FYI

**From:** jamespackardlove@gmail.com [mailto:jamespackardlove@gmail.com] **On Behalf Of** Jamie Love  
**Sent:** Monday, May 09, 2016 3:18 PM  
**To:** Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov>  
**Cc:** Claire Cassedy <claire.cassedy@keionline.org>; Fedro Paolo De Tomassi <fdetomass@gmail.com>  
**Subject:** Re: Prospective Grant of Exclusive License: Development of 5T4 Antibodies in Human Cancer Therapeutics and Diagnostics to Ovensa, Inc. ("Ovensa") located in Ontario, Canada.

Dear Rose,

Given the fact that the public has a stake in the decisions regarding licensing patents, just like the public has a stake in the decisions regarding the sale or lease of other federal assets, we request the NIH change the policy of not providing information to the public about the value of these assets, or the decision making that reached the conclusion that the license only provided the the scope of exclusive rights that were necessary for the development of the asset. I can appreciation that these policies involve a lot of people, other than you, but perhaps you can pass this along.

Can you tell me the length of the exclusive rights in the license? For example, did you license less than the life of the patent?

Jamie

On Mon, May 9, 2016 at 9:06 PM, Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov> wrote:

Dear Mr. Love,

REL0000023899

Thank you for your email regarding the referenced Prospective Grant Notice. Please see the attached response to the comments provided.

Best Regards,

Rose

---

**From:** Freel, Rose (NIH/NCI) [E]

**Sent:** Wednesday, April 20, 2016 5:01 PM

**To:** 'Jamie Love' <[james.love@keionline.org](mailto:james.love@keionline.org)>

**Cc:** Claire Cassedy <[claire.cassedy@keionline.org](mailto:claire.cassedy@keionline.org)>; Fedro Paolo De Tomassi <[fdetomass@gmail.com](mailto:fdetomass@gmail.com)>

**Subject:** RE: Prospective Grant of Exclusive License: Development of 5T4 Antibodies in Human Cancer Therapeutics and Diagnostics to Ovensa, Inc. ("Ovensa") located in Ontario, Canada.

Dear Jamie,

Thanks, your comments have been received.

Best Regards,

Rose

---

**From:** [jamespackardlove@gmail.com](mailto:jamespackardlove@gmail.com) [<mailto:jamespackardlove@gmail.com>] **On Behalf Of** Jamie Love

**Sent:** Sunday, April 17, 2016 2:24 PM

**To:** Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)>

**Cc:** Claire Cassedy <[claire.cassedy@keionline.org](mailto:claire.cassedy@keionline.org)>; Fedro Paolo De Tomassi <[fdetomass@gmail.com](mailto:fdetomass@gmail.com)>

**Subject:** Prospective Grant of Exclusive License: Development of 5T4 Antibodies in Human Cancer Therapeutics and Diagnostics to Ovensa, Inc. ("Ovensa") located in Ontario, Canada.

Rose Freel, Ph.D.  
Licensing and Patenting Manager  
Technology Transfer Center  
National Cancer Institute  
8490 Progress Drive, Riverside 5, Suite 400,  
Frederick, MD 21702  
Telephone: (301) 624-1257;

REL0000023899

Via: Email: [rose.freel@nih.gov](mailto:rose.freel@nih.gov).

Dear Dr. Freel,

Attached are our comments on the proposed license to Ovensa.

Jamie

--

James Love. Knowledge Ecology International  
<http://www.keionline.org/donate.html>

KEI DC tel: [+1.202.332.2670](tel:+12023322670), US Mobile: [+1.202.361.3040](tel:+12023613040), Geneva Mobile: [+41.76.413.6584](tel:+41764136584),  
[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

--

James Love. Knowledge Ecology International  
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KEI DC tel: [+1.202.332.2670](tel:+12023322670), US Mobile: [+1.202.361.3040](tel:+12023613040), Geneva Mobile: [+41.76.413.6584](tel:+41764136584),  
[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

---

**From:** Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=HAMMERSLAA]  
**Sent:** 5/4/2017 3:58:03 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]  
**Subject:** Kei  
**Attachments:** Response 05042017 KEI request ahmr.docx

**b5**



**b5**

**b5**

---

**From:** Vathyam, Surekha (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5ED61806C5BF4E9A819DDB37E91DEE70-VATHYAMS]  
**Sent:** 7/24/2017 5:07:24 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW: Request for Information and Comments on Prospective Grant of Exclusive Patent License: Composition and Methods for Delivering Inhibitory Oligonucleotides for the Treatment of Pancreatic Cancer, to VeriLuce Therapeutics ("VLT") located in Toronto, ON,  
**Attachments:** July 22 2017 VeriLuce Therapeutics .pdf

Hi Mark,

Just letting you know that I received the attached comments from KEI to the FR Notice for one of my exclusive license applications. I plan to: b5

Thanks,  
Surekha

**SUREKHA VATHYAM, Ph.D.**  
Senior Technology Transfer Manager,  
National Cancer Institute Technology Transfer Center  
Main: 240-276-5530  
Direct: 240-276-6865  
Email: [vathyams@mail.nih.gov](mailto:vathyams@mail.nih.gov)

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**From:** jamespackardlove@gmail.com [mailto:jamespackardlove@gmail.com] **On Behalf Of** Jamie Love  
**Sent:** Saturday, July 22, 2017 8:07 AM  
**To:** Vathyam, Surekha (NIH/NCI) [E] <[vathyams@mail.nih.gov](mailto:vathyams@mail.nih.gov)>  
**Subject:** Request for Information and Comments on Prospective Grant of Exclusive Patent License: Composition and Methods for Delivering Inhibitory Oligonucleotides for the Treatment of Pancreatic Cancer, to VeriLuce Therapeutics ("VLT") located in Toronto, ON, C...

Dear Dr. Vathyam,

Attached is a PDF of a letter responding to the Federal Register on July 10, 2017, document citation: 82 FR 31783, regarding a license on patents for the treatment of pancreatic cancer, to VeriLuce Therapeutics, located in Toronto, Ontario, Canada.

Jamie

--

James Love. Knowledge Ecology International  
<http://www.keionline.org/donate.html>  
KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,  
[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

REL0000023902

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**From:** Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]  
**Sent:** 7/31/2019 12:59:50 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Berkson, Laura (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=adb561ab47e54fdc94e2a54682514434-berksonld]  
**CC:** Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]  
**Subject:** FW: NIH licensing  
**Attachments:** govdoc20190730-203664.pdf

Hi Mark, Adrienne and Laura:

**b5**

**From:** Andrew Siddons <andrewsiddons@cqrollcall.com>  
**Sent:** Wednesday, July 31, 2019 8:00 AM  
**To:** Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>  
**Subject:** NIH licensing

REL0000023903

Hi Renate -- I hope all is well. As you are probably aware a few advocacy groups are calling attention to the NIH's licensing practices and asking for more transparency and more consideration of pricing when granting licenses... I'm referring specifically to the letter KEI sent last week (link below) and the letter that Patients for Affordable Drugs sent Tuesday (attached). Additionally, Senators Van Hollen and Scott are planning to introduce a bill related to drugs that benefit from NIH research, so I'm trying to write a story about this broader issue.

I know you can't comment on pending legislation but maybe you could comment more broadly with the NIH's position on licensing, prices and access. It would be great to get a response by early this afternoon. Thanks!

[https://www.keionline.org/wp-content/uploads/KEI Letter HouseOversightCommittee - NIH Lack of Transparency 22July2019.pdf](https://www.keionline.org/wp-content/uploads/KEI_Letter_HouseOversightCommittee_-_NIH_Lack_of_Transparency_22July2019.pdf)

Andrew Siddons

CQ Roll Call

Office: 202-650-6441

Mobile: b6

# PATIENTS FOR AFFORDABLE DRUGS<sup>TM</sup>

July 30, 2019

Dr. Francis S. Collins, M.D., Ph.D  
Director, National Institutes of Health  
9000 Rockville Pike  
Bethesda, Maryland 20892

Dear Dr. Collins,

My name is David Mitchell. I am a multiple myeloma patient and the founder of Patients For Affordable Drugs. We are the only national patient group focused exclusively on policies to lower prescription drug prices. We don't accept funding from any organizations that profit from the development or distribution of prescription drugs.

I am writing today to urge the NIH to review policies under which taxpayer-funded discoveries are licensed to private corporations that then price the drug out of reach for patients and our health system. It may have been acceptable for NIH to be indifferent to price when drugs came to market costing \$200 or \$2,000 per dose, but with new gene therapies priced at \$2 million, price must be an element of technology transfer agreements to the private sector.<sup>1</sup>

Consider the upcoming cure for Sickle Cell Disease (SCD). In March 2019, you remarked, "I am daring to say a cure for sickle cell disease may even be now at hand."<sup>2</sup>

According to NIH, American taxpayers currently spend more than \$100 million a year on research into the disease.<sup>3</sup> And an analysis by Patients For Affordable Drugs found that taxpayers invested more than \$300 million into LentiGlobin BB305 — the breakthrough treatment likely to cure sickle cell disease.

Unless appropriate guardrails are established, we are concerned that the NIH is helping to fuel our drug pricing crisis. NIH leads the breakthrough science that results in the discovery of a new drug, and then NIH licenses intellectual property to a pharmaceutical company to bring the drug to market. But NIH fails to set any guardrails on the final price of that drug, despite the significant taxpayer investment.

---

1

<https://www.bloomberg.com/news/articles/2019-04-07/gene-therapy-was-hailed-as-a-revolution-then-came-the-bill>

<sup>2</sup> <https://www.cbsnews.com/news/more-on-the-trial-aiming-to-cure-sickle-cell-60-minutes/>

3

<https://www.nih.gov/news-events/news-releases/nih-launches-initiative-accelerate-genetic-therapies-cure-sickle-cell-disease>



If the sickle treatment now under development at NIH is priced at the current going rates of \$500,000 to \$1,000,000, the cost to treat 100,000 Americans with the disease will be \$50-100 billion. With hundreds of gene therapies in clinical trials, the nation cannot possibly absorb the costs.

We are aware of the decision in the 1990s that led to a discontinuation of NIH's reasonable pricing authority.<sup>4</sup> We disagree with the conclusions drawn at that time about the impact of reasonable pricing provisions on Cooperative Research and Development Agreements (CRADAs). Regardless, times have changed, and the nation is struggling to pay for new gene therapies that may provide durable responses for cancer and potential cures. Price must be a consideration to ensure affordability and accessibility of new drugs developed with taxpayer funds.

We are calling for NIH to review how American taxpayers fund research on new medicines, how the intellectual property is transferred to drug makers, and how to ensure that our system balances incentives for innovation with prices to maximize access.

When pharmaceutical companies are allowed to price gouge for publicly funded discoveries, the American people pay three times. First as taxpayers investing in research at the NIH, second as patients at the pharmacy counter, and a third time through tax dollars that support America's largest health insurance programs, Medicare and Medicaid.

We are excited about your work to speed groundbreaking treatments to patients. Some could extend my life. But drugs don't work if people can't afford them.

Patients need your help. On July 9, 2019, Patients For Affordable Drugs launched a petition calling on the NIH to reconsider the role of the NIH in drug development and its impact on patient access. Since then, 1,344 concerned patients have signed the petition. We eagerly await your response.

Thank you for your time, consideration, and all you do for the health and wellbeing of the American people.

Sincerely,

A handwritten signature in black ink, appearing to read "David Mitchell", with a stylized, cursive script.

David Mitchell  
Cancer Patient and Founder of Patients For Affordable Drugs

---

<sup>4</sup> <https://www.nytimes.com/1995/04/12/us/us-gives-up-right-to-control-drug-prices.html>

# TAXPAYER FUNDED DRUGS & A PRICING CRISIS

SICKLE CELL TREATMENT

## PETITION TO THE NIH:

A cure for sickle cell disease is right around the corner.

But after leading the research behind the upcoming breakthrough cure, the National Institutes of Health (NIH) plans to relinquish the rights to this sickle cell research to a drug manufacturer for a small fee and without any guardrails on the final price of the drug.

We are concerned that the cure for sickle cell disease will be priced out of reach.

We are calling on the NIH to institute pricing guidelines to protect taxpayers and curb the blatant greed of drug corporations

Sign to tell the NIH: Don't sell out the sickle cell community!

Name	Date Signed	Zip Code
Reid, Samantha	7/7/19	20009
Sapp, Diane	7/9/19	33544-3207

Ledoux, Rita Ledoux	7/9/19	70518-4904
Lee, Sue	7/9/19	40014
La Rue, Pamela	7/9/19	90808
Babbitt, Susan	7/9/19	19107-6146
Meerbrey, Pamela	7/9/19	77092
Entrekin, R.K. And Linda	7/9/19	77043-4533
Sandra Rogers	7/9/19	92277
Rosalind	7/9/19	8844
Marjorie Smith	7/9/19	18322
Eric Innes	7/9/19	28211
Young, Rick	7/9/19	83607
Sproull, Charles	7/9/19	47462
Ellen McCoy	7/9/19	32940
Karen Christiansen	7/9/19	80621
Clay, Valerie	7/9/19	25309-9610
Rube, Harry	7/9/19	73301
Ackerman, Maureen	7/9/19	21776
Eag, Dawn	7/9/19	18014
Sakata, Terry	7/9/19	90803
Lowe, Carol	7/9/19	85205
Firth, Richard	7/9/19	23116-4005
Hammond, John	7/9/19	91343
Deeanne Hansen	7/9/19	56560

Hoskins, Sarah	7/9/19	60048-1610
Paula Smith	7/9/19	34275
Eells, Margaret	7/9/19	1701
Miriam Dunbar	7/9/19	81328
Ivey, Gary	7/9/19	97702-2371
Hayes, Roger	7/9/19	48239
Richard	7/9/19	37659
Hayes, Sylvia	7/9/19	48239-2946
Janine Finnie	7/9/19	30117
Dan Esposito	7/9/19	90266
Patricia Neal	7/9/19	30736
McCowen, Sean	7/9/19	32579
Mosley, Joanne	7/9/19	11218-2567
Schulof, Bob	7/9/19	11201
Lilly, Marilyn	7/9/19	76058
Vest, Narcissa	7/9/19	40356
Valerie Quercia	7/9/19	1720
Taylor, Jennifer	7/9/19	46176-8990
Karen Mobley	7/9/19	28504
Ziegler, Sharon	7/9/19	75061
Frederick Pratt	7/9/19	32608
Tenda, Kathy	7/9/19	59754
Selekman, Mayer	7/9/19	19004-2833
Elizabeth Bryson	7/9/19	33841

Catherine	7/9/19	27253
Angell, JI	7/9/19	95672
Black, Margaret	7/9/19	46227
Stern, William	7/9/19	44132-1230
Graham-Gardner, Rosemary	7/9/19	90266-1335
Christine	7/9/19	48706
Kenneth	7/9/19	80634
Anne Hallman-Perez	7/9/19	77478
Burnett, Billy	7/9/19	77632
Sue Janssen	7/9/19	44118
Annemarie Encarnacao	7/9/19	10606
Cogar, Michael	7/9/19	99347
Darlene	7/9/19	60712
Tullock, Mary	7/9/19	94928
Sheila Wentzel	7/9/19	48094
Ms. Jon Glover	7/9/19	71129
Stover, James	7/9/19	49306
Patricia Laont	7/9/19	77541
Krempa, Nancy	7/9/19	48350
Mary Mack	7/9/19	2554
Ten Broeke, Trisha	7/9/19	97267
Steenburgh, James	7/9/19	12303
Padgett, Linda	7/9/19	72758

Donna	7/9/19	98038
Stansfield, Jack	7/9/19	98292-8981
Jill L	7/9/19	29588
Stretchner, Mary	7/9/19	75211
Ashe, Bertha	7/9/19	29520
Eunice	7/9/19	53027
George Steinitz	7/9/19	91906
Ethel Lordi	7/9/19	8724
Rebecca	7/9/19	91020
Pleas, Octavia	7/9/19	66061
Jody Cundiff	7/9/19	24015
Veroune Chittim	7/9/19	97538
Sullivan, Sharon	7/9/19	60586
Kim Rosario	7/9/19	29715
Epstein, Nance	7/9/19	78634
Mitchell, Beverly	7/9/19	83709
Fraidstern, Janet Fraidstern	7/9/19	11218
Fran Tulski	7/9/19	34202
Lane, Dava	7/9/19	76017
Freeman, Beth Jane	7/9/19	11793-2658
Christopher, Ann-Marie	7/9/19	15226
Sue	7/9/19	87124
Thorne, R.	7/9/19	60123
Sunday, Lynn	7/9/19	94019

Garfield, Barbara	7/9/19	59074
Rhein, Sandy	7/9/19	70003
Peiffer, Anne	7/9/19	55412
Renka, Paula	7/9/19	78665
Lonnie Cook	7/9/19	28147
Claudia Weber	7/9/19	95926
Crumpacker, Barb	7/9/19	83814
Jackson, Sasha	7/9/19	48228
Williams, Charles	7/9/19	91932
Horner, Christopher	7/9/19	93108
Hope, Phillip	7/9/19	11215
Jardine, Elise	7/9/19	37090
Harris, Barbara	7/9/19	17821
Test, Lucy	7/9/19	20009
McKnight, John	7/9/19	92071
Harrington-Moore, Shirley	7/9/19	57104
Lynch, Diane	7/9/19	33417
Mj	7/9/19	52650
Evelyn Wells	7/9/19	53186
Virginia Vivian	7/9/19	32771
Margaret Villi	7/9/19	33410
Valeria	7/9/19	21228
Kate Sanner	7/9/19	21158
Christopherson, Bruce	7/9/19	99354



Carson-Huff, Diane	7/9/19	91702
Valeria	7/9/19	21228
Tammy Cotherman	7/9/19	16327
Caracci, Gina	7/9/19	32926-4309
Lorraine Baltimore	7/9/19	6066
Orellana, Paula	7/9/19	22204
Robin	7/9/19	21128
Wolfe, Miriam	7/9/19	3909
Robert Gloss	7/9/19	57401
Linda Demos	7/9/19	44035
Christiansen, Karen	7/9/19	80621-4550
Taylor, Marjorie	7/9/19	21795
Strand, Scott	7/9/19	54889-8903
Briselden, Patricia	7/9/19	30041
Susan Wagenblast	7/9/19	98660
Robin Cressman	7/9/19	91362
Sandy Ruffin	7/9/19	8824
Pamela Holt	7/9/19	21502
Arroyo, Mary	7/9/19	93703
Deboer, Mitchell	7/9/19	46241
Grove, Carolyn	7/9/19	28451
Phillips, Tonya	7/9/19	95670
Harris, Patricia	7/9/19	95066
Reasnor, Janis	7/9/19	74733

Leslie	7/9/19	27613
Teri	7/9/19	48240
Coulters, Kathy	7/9/19	4073
Maritza Castillo	7/9/19	1432
Tramontano, Joan	7/9/19	34293
Tramontano, Joan	7/9/19	34293
Coulters, Kathy	7/9/19	4073
Wolf, Charles	7/9/19	17522
Shaak, Susan	7/9/19	19606-2335
David	7/9/19	45786
Carolyn. Brown	7/9/19	20784
McDaniel, Stephen	7/9/19	92501
Thomas, Margaret	7/9/19	61201
James, Kathleen	7/9/19	64759
Beverly Mitchell	7/9/19	83709
Michelle Butler	7/9/19	90301
Goettel, Henri	7/9/19	64057
Linda	7/9/19	98036
Slonaker, Dena	7/9/19	91362
Robin	7/9/19	21128
Dale Holloway	7/9/19	70817
Stay, Chris	7/9/19	98020-4031
Mary Hill	7/9/19	1721
Janice Rogers	7/9/19	29078

Peg Coogan	7/9/19	14854
Yolanda Rodriguez	7/9/19	92703
Diana Sottana	7/9/19	96094
Infantino, Chuck	7/9/19	48313
Infantino, Chuck	7/9/19	48313
Madsen, Julia	7/9/19	53704
Sherman, Thomas	7/9/19	53217
M. J. Mullins	7/9/19	33442
Ervin Ortiz	7/9/19	19602
Karen	7/9/19	48137
Stanton, Pamela	7/9/19	21520
Hegeman, Eli	7/9/19	10024
Katsarelis, Kathy	7/9/19	95123
Jean Gregory	7/9/19	20617
Candie Glisson	7/9/19	47906
Fernandez, Jeffrey	7/9/19	74875-7796
Acosta, Peggy	7/9/19	19567
Barbara Olson	7/9/19	45050
Marie	7/9/19	64081
Jeffrey Nelson	7/9/19	92104
Leigh Dolin	7/9/19	98042
Robert Fowler	7/9/19	44039
Peter F. Trovesi Jr	7/9/19	98328
Shumway, Megan	7/9/19	95821

Alice Hudson	7/9/19	38002
Edwards, Shara	7/9/19	89128
Juliana Keeping	7/9/19	20910
Young, Aleem	7/9/19	46218
Witsen, Harry	7/9/19	33446
Jensen, Dan	7/9/19	97133
Susan Field	7/9/19	21030
Megan Eggleston	7/9/19	78240
Frank Lamborn	7/9/19	91701
Deb	7/9/19	99218
Sallmen, Hank	7/9/19	16124
Ansari, Christine	7/9/19	24464
Kevin Ororke	7/9/19	98070
Judith L. Miller	7/9/19	45251
Chey Richmond	7/9/19	32503
Tracey	7/9/19	92082
Handa, Sharon	7/9/19	94131-1034
Schreck, Margret	7/9/19	85375-4240
Kathleen Richardson	7/9/19	37214
Sherry Weinstein	7/9/19	80127
Verneda Lights	7/9/19	29935
Jensen, Lisa	7/9/19	17520
Chavolla, Linda	7/9/19	94513
Colton, Jenn	7/9/19	20005

Colton, Jenn	7/9/19	20005
Batchelder, Carol	7/9/19	2914
Deenna Kimmer	7/9/19	52070
Rhonda Williams	7/9/19	21502
Wells, Carol	7/9/19	89444
Charlotte Alexandre	7/9/19	80229
Edythe Mostin	7/9/19	91367
Bell, Patricia	7/9/19	95709
Sherry Post	7/9/19	99706
Jensen, Cindy	7/9/19	97133
Evans, Debbie	7/9/19	33440
Colton, Jenn	7/9/19	20005
Cutter, Michael	7/9/19	99515
Latrease	7/9/19	92105
Murdock, Katherine	7/9/19	72737-0038
Marsha Flood	7/9/19	60563
Anne Stangeland	7/9/19	97365
Daniel Belachew	7/9/19	2139
Hull, Gary	7/9/19	84405
Kathleen Thompson	7/9/19	75964
Joan Donnaway Bsn	7/9/19	81326
MacEdon, Karen	7/9/19	95823
Paula D Murphy	7/9/19	65355

Carol	7/9/19	92394
Jeanne Robinson	7/9/19	2747
Schultz, Joyce	7/9/19	56121
Jan Garber	7/9/19	19380
Mark	7/9/19	60586
James Marlow	7/9/19	98498
Lampke, Karen	7/9/19	80526-2358
Kyra Legaroff	7/9/19	10029
Marlene Heytvelt	7/9/19	98366
John Allison	7/9/19	23664
Jim O'Toole	7/9/19	55906
Linden, S. A.	7/9/19	43224-2645
Candic	7/9/19	14467
Gribble, C	7/9/19	53207
Ceron, Efren	7/9/19	21403
Laquieda	7/9/19	85295
Insley, William	7/9/19	98407
Lang, Belinda	7/9/19	35204
Doris	7/9/19	28904
Barbara Warren	7/9/19	16601
Woods, Patsy	7/9/19	92647
Hair, Caroline	7/9/19	29229-4329
Samuel Blue Jr	7/9/19	23669
Klimczak, Matthew	7/9/19	60516
Donna Payon	7/9/19	92064
Fox, Mark	7/9/19	32822

Will, Leona	7/9/19	33015-6233
Della Kern	7/9/19	18109
Sharon Fowler	7/9/19	32244
Malinda, Lee	7/9/19	99201
Hulke, Bonnie	7/9/19	60107
Steeves, Charleen	7/9/19	90290
Cadwallader, Jane	7/9/19	80439
David Matthew Bailey	7/9/19	70818
Brewer, Sandra	7/9/19	60013
Manuel, Juliette	7/9/19	97006
Schultz, Arnold	7/9/19	80012
Schatz, William	7/9/19	32164
Cobb, Sandra	7/9/19	44022
Mosley, Michelle	7/9/19	55346
Blum, Eugene	7/9/19	53147
Carolyn Griswold	7/9/19	37404
Gorman Rn, Bonnie	7/9/19	2169
St. John, Lee	7/9/19	92313
Andrew Lyall	7/9/19	78415
Sica, Helen	7/9/19	49682
Lynch, Linda	7/9/19	86301
Janice Schwartz	7/9/19	19008
Payne, Arthur	7/9/19	76014-1527



Joan Gustafson	7/9/19	90807
Alan	7/9/19	2139
Moreno, Linda	7/9/19	85326
Koritz, Mark	7/9/19	30338
Zorrilla, Pilar	7/9/19	91307
Meadow, Melissa	7/9/19	91362
Worcester, Chris	7/9/19	89509
Myrna Guthrie	7/9/19	16830
Bleile, Mike	7/9/19	92646
Martien, Rebecca	7/9/19	80021-4503
Harper, Barbara	7/9/19	95012
Noel, Letitia	7/9/19	60610
Roy Peterson	7/9/19	48362
Lowe, Kay	7/9/19	80233
Roshan Akula	7/9/19	91007
Fast, Phyllis	7/9/19	7933
Ali	7/9/19	11214
Hawthorn, Pat	7/9/19	54843
Melton, Kathryn	7/9/19	77536
Jimmie	7/9/19	21061
Carlin, Patricia	7/9/19	46122
Bindig, Diane	7/9/19	8052
Martha Racketta	7/9/19	44688
McCart, Ela McCart	7/9/19	30655
Al Liebeskind	7/9/19	19966

Marlis Moore	7/9/19	50047
Frankel, Andrea	7/9/19	95959
Brown, Antoinette	7/9/19	95206
Janet Bachelor	7/9/19	32730
Stan Janzick	7/9/19	10465
John Rippy	7/10/19	37141
Ryan Taylor	7/10/19	
Cottrill, Craig	7/10/19	98059
Paula Suriano	7/10/19	99208
Stephen Wheeler	7/10/19	81212
Irenei	7/10/19	43220
Lisa Zarafonetis	7/10/19	75214
Ewaskey, Daniel	7/10/19	90808
Michael Milam	7/10/19	26202
Andrea Adaway	7/10/19	77422
Donald Sawyer	7/10/19	77384
Linda May	7/10/19	21234
James Roberts	7/10/19	75205
Amy Mason Cooley	7/10/19	36604
Clayton Martin Jr	7/10/19	32205
Tamica	7/10/19	33440
Jasmine Hightower	7/10/19	36301
Chifuan Head	7/10/19	20019
Omolola Abikoye	7/10/19	30296

Ezraline Hubbard	7/10/19	71106
Miele, Danielle	7/10/19	01845-1308
Alexsis	7/10/19	29916
Copper	7/10/19	61103
Sherita Yancey	7/10/19	23462
Tabatha Marmon	7/10/19	38116
Michael Thomas	7/10/19	30083
Brittney Wells	7/10/19	33901
La Shanna Mosley	7/10/19	36605
Javair	7/10/19	70058
Jarem Lloyd	7/10/19	28208
Jamyr Davis	7/10/19	28208
Reginald Thomas Jr	7/10/19	28208
Felecia	7/10/19	61104
Cynthia	7/10/19	13820
Susan Sanforz	7/10/19	95076
Ashebia	7/10/19	11249
Mary Moore	7/10/19	46239
Merkimberly Bender	7/10/19	36105
Tameeka Mitchell	7/10/19	28303
Paul Kleutghen	7/10/19	28461
Martinez Sr., Marty	7/10/19	80022-2916
Nephritina	7/10/19	30310
Andrea	7/10/19	15868
Janeal Grant	7/10/19	38114

Esther Jubert	7/10/19	33624
Angela	7/10/19	70124
Georgene	7/10/19	89183
Monica Meadors	7/10/19	94572
Frankie	7/10/19	33680
Tyrone McQueen	7/10/19	36617
Roshawn Bedford	7/10/19	77078
Joshua May	7/10/19	35242
Hermosillo, Nicholas	7/10/19	92346
Kenya Thomas	7/10/19	70814
Roberta R Czarnecki	7/10/19	98204
Jasmine Smith	7/10/19	75150
Tineshia Jennings	7/10/19	33805
Jacquelyne Walker	7/10/19	60628
Cheryl Odonnell	7/10/19	2916
Wiersma, Jess	7/10/19	56537
Jeff Grayson	7/10/19	7060
Ann Grayson	7/10/19	7060
Martinez Sr., Marty	7/10/19	80022-2916
Patti Tsokolas	7/10/19	60465
Angus, Billy	7/10/19	59840
Ron	7/10/19	45306
Tiffany Moore	7/10/19	68521
Emerich, Mary	7/10/19	54130

Emerich, Walter	7/10/19	54130
Jerome	7/10/19	10039
Jane	7/10/19	62995
Lashonda Edwards	7/10/19	21133
Kim Howard	7/11/19	95616
Angela	7/11/19	85323
Spring Gombe-G^tz	7/11/19	
Lakendra	7/11/19	38118
Trabulus, Lucy	7/11/19	10011
Warner, Cheryl	7/11/19	44875
Rebecca L Oakes	7/11/19	16601
Mariah Wormley	7/11/19	50266
Levon Rudolph	7/11/19	36432
Jernigan, Gloria	7/11/19	90030
Shakeira Wesley	7/11/19	30339
Vince Mendieta	7/11/19	78715
Lashenna Smith	7/11/19	39059
Carrie Kraus	7/11/19	98122
Kraus, Carrie	7/11/19	98122
Vera Hutchison	7/11/19	47975
Donald	7/12/19	36265
Cesar Lopez	7/12/19	91701
Carr, Paula	7/12/19	24401
Mary Sexton	7/12/19	63128

Martin, Julie	7/12/19	54837
Judith Rowland	7/12/19	32563
Jenkins, Robin	7/12/19	97338
McMurtrey, Anita	7/13/19	93221
Bush, Elizabeth	7/13/19	6010
Virginia Shannon	7/13/19	93908
Bixter, Pam	7/13/19	80439-8975
Diana Montgomery	7/14/19	13601
Cortney Sanders	7/14/19	34748
Sarane James	7/14/19	10466
Donna Benfatti	7/15/19	18424
Duhart Clarke, Sarah	7/15/19	27606
Potter, Harry	7/15/19	94404
Potter, Harry	7/15/19	94404
Struble, Vickie	7/15/19	76179
Susan Fariss	7/15/19	20003
Bobette	7/16/19	70126
Sloan, Nina	7/16/19	21218
Mae	7/16/19	21217
Sandra	7/16/19	48911
Jeanne	7/16/19	48223
Diane Madigan	7/16/19	21229
Margaret Williams	7/16/19	21216
Eleanor	7/16/19	48316

Sandra Jurus	7/16/19	21102
Battersby, Patricia	7/16/19	48301
Beverley Mignott	7/16/19	21286
Olatunji Mwamba	7/16/19	17356
Randy Anderson-Orr	7/16/19	70058
Vera	7/16/19	38118
Charlotte Kelly	7/16/19	48503
Jazmine	7/16/19	70058
Shannon, Debbie	7/16/19	48439
Suzanne Holtz	7/16/19	36092
Nathan	7/16/19	36109
Rollins, Juanita	7/16/19	21208
Ed Jackson	7/16/19	36109
Sherry	7/16/19	48327
Eileen Atkins	7/16/19	21286
Earline McFadden	7/16/19	48503
Prince, India	7/16/19	35234
Juanita Jenkins	7/16/19	36109
Bw	7/16/19	70124
Deborah H. Reeves	7/16/19	38119
Linda	7/16/19	48910
Robert Hodges	7/16/19	38655
Hudgins, Bobbie	7/16/19	48206
Renfro, Donna	7/16/19	38109

Cassie	7/16/19	97303
Lorraine	7/16/19	21209
Gladys Wooters	7/16/19	21222
Ernest Fleming	7/16/19	70127
Vanessa	7/16/19	21225
Keating, Louise	7/16/19	21244
David McSwain	7/16/19	70032
Roseann Wainwright	7/16/19	28303
Norma Jean	7/16/19	48224
Audrey Brown	7/16/19	48334
Nancy Barnes	7/16/19	48238
Verneda Lights	7/16/19	29935
Marsha Flood	7/17/19	60563
Edwina Stillings	7/17/19	35206
Kenneth Hess	7/17/19	21009
Gary	7/17/19	38111
Mary	7/17/19	38134
Arlette Williams	7/17/19	70471
Jennifer	7/17/19	48146
McCall, Rufus	7/17/19	45231
Perrin	7/17/19	94541
Despina Christakis	7/17/19	70005
Deborah Freeman	7/17/19	38111
Clairesa Adams	7/17/19	35071



Gold, Amy	7/17/19	21209
Lyall, Andrew	7/17/19	78415
Swanson, Laurie	7/17/19	33051
Simmons, Diana	7/17/19	21234
William R. Sexton	7/17/19	44113
Lagassey, Michael	7/17/19	33603
Ziegler, Sharon	7/17/19	75061
Degenhart, Dm	7/17/19	80504-3918
Betty	7/17/19	31520
Cadwallader, Jane	7/17/19	80439
Andrew Paterson	7/17/19	2145
Echols, Anne	7/17/19	98034
Eileen	7/17/19	6413
Krajec, Debra	7/17/19	53051
Veroune Chittim	7/17/19	97538
H. Dennis Shumaker	7/17/19	17547
Raitt, Jacob R.	7/17/19	6605
John	7/17/19	40204
F., J.	7/17/19	44839
Lintz, Barbara	7/17/19	93256
Brannan, Sandra	7/17/19	79109
Hull, Juanita	7/17/19	84405
Frauenhofer, Ann	7/17/19	21222
Denise Phelps-King	7/17/19	37135

Rhonda	7/17/19	70458
Sasha Jackson	7/17/19	48228
Tenda, Kathy	7/17/19	59754
Christine Cross	7/17/19	93436
Kathleen Hynes	7/17/19	94109
Sinai, Iris	7/17/19	07746-1687
Rutherford, Richard	7/17/19	24401
Tran, Sheila	7/17/19	55122
Catherine Rogers	7/17/19	46163
Christine Etapa	7/17/19	60632
Heather	7/17/19	49426
Hull, Gary	7/17/19	84405
Dan Esposito	7/17/19	90266
Garcia, Armando A.	7/17/19	92571
Randall Rivas	7/17/19	32205
Liberge, Marcel	7/17/19	97527
Jane Miller	7/17/19	62995
Schnaidt, Sue	7/17/19	7442
Diana	7/17/19	32233
Mueller, Dabney	7/17/19	89523
Joanne Groshardt	7/17/19	75081
Goldschen, Stacy	7/17/19	60031
Domb, Doreen	7/17/19	95945
Lykins, Jim	7/17/19	97056

Cozine, Deborah	7/17/19	51012
Jane	7/17/19	8003
Moore, Debra	7/17/19	26143
Daniel Belachew	7/17/19	2139
Heinemann, Denine V	7/17/19	97217
Venidis, Maria	7/17/19	12402
Bentley, Kathleen	7/17/19	98331
Melissa	7/17/19	93561
Ehli, Dawn	7/17/19	27519
Kristen Myford	7/17/19	29483
Dayle Severns	7/17/19	24538
Ronald	7/17/19	48867
David J Galbraith Md	7/17/19	16602
Tovar, John	7/17/19	50613
Stephens, Kyle	7/17/19	84321
Kovacsiss, John	7/17/19	44648
Daniels, Linda	7/17/19	75180
O'Brien, Daniel	7/17/19	12547
S	7/17/19	90036
Thompson, Sandy	7/17/19	97703-5288
Mollin, Kimberly	7/17/19	92064
Betty	7/17/19	85719
Melton, Kathryn	7/17/19	77536

Fernandez, Jeffrey	7/17/19	74875-7796
Mary Helen	7/17/19	32312
Maxine	7/17/19	90405
Barbara Pelowski	7/17/19	53132
Firth, Richard	7/17/19	23116-4005
Alyse	7/17/19	33324
Cannon, Olivia	7/17/19	42069
Louise	7/17/19	1702
Sabatini, Frank	7/17/19	18643
Krug, Ilana	7/17/19	21239
Bouhedda, Mustapha	7/17/19	94061
Tom	7/17/19	95350
David	7/17/19	60641
Lane, Dava	7/17/19	76017
Janet Wheeler	7/17/19	19403
Payne, Arthur	7/17/19	76014-1527
Wieland, Loren	7/17/19	33954
Taylor, Ron	7/17/19	85122
Thornton, Keith	7/17/19	76137
Chaffin, Claudia	7/17/19	78626
Ahern, Michael	7/17/19	44026
Aguirre, Mary	7/17/19	77031
Blue, Samuel	7/17/19	23669
Angell, JI	7/17/19	95672
Monica Meadors	7/17/19	94572

Blum, Eugene	7/17/19	53147
Bates, Gina	7/17/19	44606
Jerroll	7/17/19	28655
Johnson, Carol	7/17/19	60542
Matthews, Virgil E.	7/17/19	25314
Hathaway, Melissa	7/17/19	97230
White, Katherine	7/17/19	20855
Brian	7/17/19	54880
Kathleen	7/17/19	70722
Cobb, Sandra	7/17/19	44022
Labonte, Edwina	7/17/19	27834
Teresa A Kohl	7/17/19	60901
Diane J Donnellan	7/17/19	97146
Quinlan, Mary	7/17/19	70065
Gary Ameika	7/17/19	4064
Harris, Shirlene	7/17/19	78249
Caroline Franceski	7/17/19	20854
Carone, Courtney	7/17/19	48146
Hochberg, Adrienne	7/17/19	33477
Karen Christiansen	7/17/19	80621
Schweyen, Veronica	7/17/19	10520
Andarmani, Kristine	7/17/19	95070-3329
Lanna Ultican	7/17/19	64015

Bobb, Rebecca	7/17/19	85739
Mobley, Henry	7/17/19	23464
Camele, Mary	7/17/19	45140
Warren, Grady	7/17/19	38464
Booth, Heather	7/17/19	20007
Grotzky, Sheila	7/17/19	80543
Granlund, Fred	7/17/19	91601
Phillip Hlavac	7/17/19	32756
Claudia Perez	7/17/19	85339
Katherine Wright	7/17/19	97068
J. Michael Henderson	7/17/19	93405
Angela	7/17/19	70124
Cecilia	7/17/19	14020
Mary Mack	7/17/19	2554
Scott, Wendy	7/17/19	44460
Roger	7/17/19	92064
Vicki And Rod	7/17/19	92107
Kathleen	7/17/19	2062
Ruby Hernandez	7/17/19	91764
Dawn	7/17/19	53219
Spoon, Leslie	7/17/19	93402
Lytle, Charles	7/17/19	76011
Myron Morgan	7/17/19	76137
Cooney, Margaret	7/17/19	2360

Romaine, Caridad	7/17/19	11706
Debra Greenfield	7/17/19	82007
Kasmira, Sharon	7/17/19	53548
McDaniel, Stephen	7/17/19	92501
Brickman, Judith	7/17/19	8648
Jackie Trapp	7/17/19	53150
Juli Hamilton	7/17/19	46319
Grossi, Joanne	7/17/19	8701
Robert Pollitz	7/17/19	84105
Lonn	7/17/19	3825
Christine Rivera	7/17/19	94521
Ruth	7/17/19	82001
Jill Gonsberg	7/17/19	78602
Lascko, James	7/17/19	44102-4696
Chaney, Debbie	7/17/19	78259
Kim, Justin	7/17/19	94404
J Gebhardt	7/17/19	83204
Meerbrey, Pamela	7/17/19	77092
Nicole P Walsh	7/17/19	4578
Donovan, Elaine	7/17/19	52405
Wiley, Jane	7/17/19	33624
Ferrel, Connie	7/17/19	83634
Hull, Lise	7/17/19	97411
Franklinknox	7/17/19	21742

Epstein, Nance	7/17/19	78634
Wright, Susan	7/17/19	29078
Elinore	7/17/19	21218
Otoole, Lucretia	7/17/19	35023
Debbie	7/17/19	73754
Frankie	7/17/19	33680
Bustillos, Madeline	7/17/19	91732
Henson, Lana	7/17/19	73106
Byers, P	7/17/19	86401
Sharon Haney	7/17/19	60525
Catherine Twiss	7/17/19	1256
Linerud, Tim	7/17/19	94002
Wardell, Tom	7/17/19	19147
Evelyn Griffin	7/17/19	82523
White, Valarie	7/17/19	77284
Johanna Schroth	7/17/19	70808
Gorman Rn, Bonnie	7/17/19	2169
Carmody, Judith	7/17/19	34224
Copenhaver, Pat	7/17/19	50126
Watson, Toni	7/17/19	91977
Hair, Robin	7/17/19	17020
Chitra	7/17/19	21044
Chitra	7/17/19	21044
Jean Cameron	7/17/19	77845
Nyiri, Leslie	7/17/19	19038



Christie Heitman	7/17/19	57106
Sherlynn Miller	7/17/19	8741
Joan Stanton	7/17/19	12186
Clifford, William	7/17/19	17112
Kilgore, Nancy	7/17/19	98501-1061
Janet Lawson	7/17/19	45409
Ide, Parnel	7/17/19	4673
Stepzinski, Linda	7/17/19	60046
Entrekin, R.K. And Linda	7/17/19	77043-4533
O'Shea, Lynn	7/17/19	70119
Marian	7/17/19	29910
Rozner, Judith	7/17/19	10543
Beth Wheeler	7/17/19	1772
McClintock, Gloria	7/17/19	98274
Lewis, Stewart	7/17/19	11743
Gribble, C	7/17/19	53207
Jensen, Dan	7/17/19	97133
Kehrein, Barbara	7/17/19	53716-2308
Christopher, Ann-Marie	7/17/19	15226
Garold	7/17/19	41014
Meyer, Christina	7/17/19	67401
Putnam, Judi	7/17/19	92065
Donna	7/17/19	90505
Howard Andreasen	7/17/19	32904

Hickman, Cheryl	7/17/19	59808
Russ, Louis	7/17/19	35204
Elaine Laffan	7/17/19	2482
Hansberry, Robert	7/17/19	17404
Burrows, N	7/17/19	99508-1438
Gillilan, Jennifer	7/17/19	5448
Shirley	7/17/19	60061
Rozalind	7/17/19	92284
Knuth, Lilly	7/17/19	11530-5211
Frances Forman	7/17/19	77904
Cox, Allison	7/17/19	98070
Gaiefsky, Cheryl	7/17/19	32750-3079
Mort	7/17/19	49546
Janet Barry	7/17/19	34669
Harrell, Roger H.	7/17/19	90254
Mitchell, Beverly	7/17/19	83709
Koritz, Mark	7/17/19	30338
Ronald G Thompson Sr	7/17/19	21084
Danna Griffith	7/17/19	97446
Chifuan Head	7/17/19	20019
Edward Roten	7/17/19	17566
Sharon Lundin	7/17/19	37917
Adelman, Barry	7/17/19	32967
David Matthew Bailey	7/17/19	70818

Hannon, Kenneth	7/17/19	39046-9137
Marie Juarez	7/17/19	91304
Kegley, Lori	7/17/19	2703
Vincent, Ronnie	7/17/19	19977
Ganmoryn, Croitiene	7/17/19	34480-8122
Hair, Caroline	7/17/19	29229-4329
Ronald J. Wolniewicz	7/17/19	43609
La Rue, Pamela	7/17/19	90808
Elizabeth	7/17/19	45414
Nancy Mulrey	7/17/19	2149
Kimberly	7/17/19	48212
Teresa Ota	7/17/19	78665
Ellen Morgan	7/17/19	33756
Virginia Turner	7/17/19	91367
Eric	7/17/19	33498
Alice Hudson	7/17/19	38002
Norma Jean	7/17/19	48224
Harper, Barbara	7/17/19	95012
Felicity Devlin	7/17/19	98406
Fran McDonough	7/17/19	33774
Sheppard, Sally	7/17/19	19002
Donald Sawyer	7/17/19	77384
Sykes, Freddie	7/17/19	37178-5130
Reynolds, Michele	7/17/19	48237-1552

Rosario, Kim	7/17/19	29715
David L. Altman	7/17/19	46783
Fraker, Laurie	7/17/19	92243
Robert	7/17/19	45120
David L. Altman	7/17/19	46783
Peiffer, Anne	7/17/19	55412
Darovic, Elizabeth	7/17/19	93940
Lynn	7/17/19	97045
Sarah	7/17/19	48073
Linden, S. A.	7/17/19	43224-2645
Marjorie Smith	7/17/19	18322
Napoleon, Alexandra	7/17/19	19067
Fenslage, Linda	7/17/19	44004
Strand, Scott	7/17/19	54889-8903
Lilly, Marilyn	7/17/19	76058
Chris Williams	7/17/19	77539
Brown, Harold	7/17/19	44103
Brown, Harold	7/17/19	44103
Sue	7/17/19	54212
Beverly	7/17/19	16936
Davis, Mary	7/17/19	97206
Boyles, Nathan	7/17/19	29681
Poe, Edgar	7/17/19	48192
Guadalupe	7/17/19	78617
Carol	7/17/19	94591

O'Neill, John	7/17/19	33309
Cloyd, Irene	7/17/19	08012-1209
Tsokolas, Patti	7/17/19	60465
Lisa	7/17/19	53511
Beaulieu, Richard	7/17/19	33317-7625
Richard Cormican	7/17/19	46254
Smith, Jackie	7/17/19	43207
Lindsey, David	7/17/19	42320
Graff, Wanda	7/17/19	97013
Stepanian, Ara And Sheryl	7/17/19	49417-1817
D.K. Hodges Hull	7/17/19	20906
Ronald.S	7/17/19	10465
Gerrienne Rodgers	7/17/19	94553
Knipmeyer, Sue	7/17/19	81506-1989
Ilya Speranza	7/17/19	11233
Linda Daly	7/17/19	12534
Battin, Meldon	7/17/19	66071
Bill	7/17/19	66608
Dorothy	7/17/19	33616
Irene	7/17/19	66608
Goodman, Laney	7/17/19	1740
Lowe, Kay	7/17/19	80233
Michelle Mueller	7/17/19	98133
Peg Schurr	7/17/19	75234

Marla Jaramillo	7/17/19	94590
Areal Rives	7/17/19	62401
Allen, Barb	7/17/19	55437
Toby Ann Reese	7/17/19	44280
Hoffman, Gilbert	7/17/19	97003
Diaz, Sue	7/17/19	30813
Mattusch, Linda	7/17/19	80304-2848
Novak, Trina	7/17/19	2492
Fitch, Karen	7/17/19	45503
Annemarie Encarnacao	7/17/19	10606
Nick, Patricia	7/17/19	26003
Octavia Pleas	7/17/19	66061
Karl	7/17/19	19149
Merikay Jones	7/17/19	76542
Hensman, Kathleen	7/17/19	33445
Dalia Hunter	7/17/19	78132
Lizer, Henry	7/17/19	33837
Thomas	7/17/19	36869
Patricia	7/17/19	77531
M	7/17/19	85201
Anderson, Tom	7/17/19	33334
Lesley, Mike	7/17/19	35206
Dittmar, Magdalena	7/17/19	98023
Sheheen, Diane	7/17/19	29078-9747
Joanne Coakley	7/17/19	43614

John	7/17/19	46815
Mary Beth Wimberley	7/17/19	38222
Byron Jadan Ceasar	7/17/19	77088
Kathy Sandberg	7/17/19	14527
Talley, April	7/17/19	50575
Mohrmann, Ann	7/17/19	72227
Anderson, Betty	7/17/19	42103
Lang, Michelle	7/17/19	55117
Moore, Vivian	7/17/19	21502
Stansfield, Jack	7/17/19	98292-8981
Karen Gerlach	7/17/19	37128
Reinfried, Kay	7/17/19	17543
Klimczak, Matthew	7/17/19	60516
Theresa Bass	7/17/19	19149
Kori	7/17/19	14420
Claus, Nancy	7/17/19	60187-3087
Keltz, Denese	7/17/19	91335
Jennifer	7/17/19	40324
Ten Broeke, Trisha	7/17/19	97267
Johnson, Steven	7/17/19	99212
Anna Y	7/17/19	94044
Dixon-Dybvad, Laura	7/17/19	98107
Diana	7/17/19	12550

Romero, Tony	7/17/19	10036
Shirley, Donna	7/17/19	40272
Lacayo, Yina	7/17/19	33126-2855
Robert	7/17/19	60626
Schwartz, Janice	7/17/19	19008-1709
Freeman, Beth Jane	7/17/19	11793-2658
Yvonne Augustus	7/17/19	11769
Stark, Jan	7/17/19	92683
Hattie	7/17/19	60644
Eva Stern	7/17/19	10550
Marilee	7/17/19	97302
Boveda, Julio	7/17/19	33065
Artman, Cara	7/17/19	63146
Ahlstrom, Anne	7/17/19	84341-2912
Denise	7/17/19	2909
Debbie D	7/17/19	20659
Sheryl Anderson	7/17/19	92110
Hulke, Bonnie	7/17/19	60107
Audrey C Dickens	7/17/19	27534
Shayne, Vivian	7/17/19	34112
Bentley, Judith	7/17/19	97338
Janczuk, Stan	7/17/19	10465
Bentley, Judith	7/17/19	97338
Kay	7/17/19	91202



Lusby, Deborah	7/17/19	92505
Burge, Sharon	7/17/19	97306
Stacey Dillingham	7/17/19	40245
Lafrance, John	7/17/19	48088
Rucker, Sandra	7/17/19	37207
Isabelle	7/17/19	75248
Emerich, Mary	7/17/19	54130
Emerich, Walter	7/17/19	54130
Olson, Barbara	7/17/19	45050
Hodapp, Anne	7/17/19	15140
Schatz, William	7/17/19	32164
Marlene Heytvelt	7/17/19	98366
Padgett, Linda	7/17/19	72758
Burke, Sally	7/17/19	53228-2379
Hope, Phillip	7/17/19	11215
Mary Sexton	7/17/19	63128
Bixter, Pam	7/17/19	80439-8975
Rachel	7/17/19	19027
Peggy	7/17/19	90291
Janet	7/17/19	10032
Heide, Angie	7/17/19	97214
Kosbab, Rebecca	7/17/19	55306
Krempa, Nancy	7/17/19	48350
Noel, Letitia	7/17/19	60610

Annoni, Pat	7/17/19	84047
Gina Hamlin	7/17/19	21629
Rhein, Sandy	7/17/19	70003
Yombik, Carol	7/17/19	48507
Hassett, Gerald	7/17/19	11104-2263
Barker, Deborah	7/18/19	38134
Johnston, Michael A.	7/18/19	92116
Starr, Guinevere	7/18/19	92270
Kline, Daniel	7/18/19	94105-2638
Candie Glisson	7/18/19	47906
Sims, Mary	7/18/19	45387-1313
Yvonne Marley	7/18/19	85381
Marsha	7/18/19	11553
Laura	7/18/19	10001
Sharpe, Robyn	7/18/19	2126
Susan Schneider	7/18/19	10956
Benjamin Edwards	7/18/19	64113
Frederick, Jean	7/18/19	80904-1811
Helen Rohlfing	7/18/19	21229
Susan Schneller	7/18/19	8648
Elaine Barrett	7/18/19	92103
Bobette	7/18/19	70126
Robert Fingerman	7/18/19	37356
Michelle	7/18/19	32257

Stephen Wheeler	7/18/19	81212
Stefanie Castleman	7/18/19	75082
Laura Tartanella	7/18/19	91016
Charlene	7/18/19	10314
Dominique Curtis	7/18/19	8857
Sarah	7/18/19	60153
Koritz, Raleigh	7/18/19	55442
Roy	7/18/19	66104
Telford Pearce	7/18/19	23237
Betty Thompson	7/18/19	11368
Joann Withers	7/18/19	67005
Patricia Goodkin	7/18/19	10314
Alexandre, Charlotte	7/18/19	80229-8450
Robyn Kassner	7/18/19	11747
Linda May	7/18/19	21234
Rodriguez, Ana	7/18/19	11356
Coulter, Craig	7/18/19	94904
Doppelhammer, Diane	7/18/19	56007
Erin	7/18/19	60630
Barbara Brooks	7/18/19	55387
William Rohde	7/18/19	2116
Ramble, Kirk	7/18/19	17404
Kirk A. Ramble	7/18/19	17404

Hershman, Connie	7/18/19	19128-4249
Steven Hadfield	7/18/19	28212
Chamberlain, Ross	7/18/19	89108
Lannette Foster	7/18/19	93933
Wright, Susan	7/18/19	44827
Sasha	7/18/19	11217
Grady	7/18/19	34652
Bw	7/18/19	70124
Jeanette Stuart	7/18/19	11779
Wayne	7/18/19	11722
Alex	7/18/19	10009
Griswold, Carolyn	7/18/19	37404
Fran Howse	7/18/19	97005
Mosley, Joanne	7/18/19	11218-2567
Martha Perkins	7/18/19	91107
Green, Patricia	7/18/19	19147
Licata, Phyllis	7/18/19	60706
Sarah	7/18/19	19090
Loving, Cheryl	7/18/19	77057
Dora	7/18/19	48912
Wendell Hardesty Sr	7/18/19	21224
Jill	7/18/19	10009
Kathleen Flanigan	7/18/19	85020
Ellen McCoy	7/18/19	32940

Mick, Marilyn	7/18/19	78239
Arellys Feliz	7/18/19	33190
Hinkle, Melinda Hinkle	7/18/19	92335
Daniel	7/18/19	49508
Paula	7/18/19	70520
Linda	7/18/19	32967
Dorthy	7/18/19	54701
Hendricks, Dixie Lee	7/18/19	64772
Linda Chewning	7/18/19	31601
Maureen	7/18/19	8004
Ronna	7/18/19	98409
Skidmore, Carla And Robert	7/18/19	1201
Kerry	7/18/19	90802
Linda	7/18/19	22724
Lucero, Donna	7/18/19	80120
Bj	7/18/19	66203
Susan	7/18/19	98031
Liniman, Cheryl	7/18/19	44130
Bethany	7/18/19	37692
Stephen	7/18/19	92530
Christine	7/18/19	33803
Coolidge, Anita	7/18/19	92007
Pantier, Gina	7/18/19	98003
Donna Barr	7/18/19	32750

Carolyn Brooks	7/18/19	48130
Ardy	7/18/19	99320
Melissa	7/18/19	46052
Hodges, Gaye	7/18/19	21216
Ralph	7/18/19	90262
Lynnette	7/18/19	46544
Debra Henderson	7/18/19	45013
Bloczynski, Cynthia	7/18/19	53704
Kim Burrow	7/18/19	38478
Barbara	7/18/19	62704
Vicki Russo	7/18/19	15143
Wendy	7/18/19	50446
Al Liebeskind	7/18/19	19966
Terelle	7/18/19	95519
Darlene	7/18/19	77587
Watkind, Liz	7/18/19	26003
Jenkins, Robin	7/19/19	97338
Angela Rush	7/19/19	27407
Valerie	7/19/19	4103
Mary	7/19/19	97405
Rhyanna	7/19/19	97389
Marian	7/19/19	89183
Viola Tovar	7/19/19	97756
Linda Edwards	7/19/19	83815
L A Keel	7/19/19	53704
Sharon	7/19/19	49202
Carr, Paula	7/19/19	24401

Vince Mendieta	7/19/19	78715
Robert	7/19/19	66614
Lisa Zarafonetis	7/19/19	75214
John Lunza	7/19/19	14701
Sharon	7/19/19	33409
Will	7/19/19	30047
Mike	7/19/19	78726
Christopher Collopy	7/19/19	19372
Satwath	7/19/19	60561
Laura	7/19/19	57718
Linda Brazell	7/19/19	93256
Bonnie Trier	7/19/19	19365
Hopkins, Kathee	7/19/19	84165
James	7/19/19	61201
Barbara	7/19/19	57719
Marie	7/19/19	46268
Janis	7/19/19	64093
Meredith	7/19/19	20151
Eells, Margaret	7/19/19	1701
Dana	7/19/19	68124
Teed, Deborah	7/19/19	32827
David	7/19/19	1702
Schechter, Deborah	7/19/19	60645
Lynn	7/19/19	97086
Darlene	7/19/19	33142
Mary	7/19/19	10520

James	7/19/19	98664
Rebecca Gambill	7/19/19	45365
Jean	7/19/19	49058
Carol Mongiello	7/19/19	8067
Valerie	7/19/19	54770
Karen	7/19/19	85711
Beth	7/19/19	48236
Joseph	7/19/19	8078
James Maloney	7/19/19	31411
Michael	7/19/19	53219
Cheryl	7/19/19	64733
Tricia	7/19/19	61036
Jo Nowakowski	7/19/19	14850
Margaret	7/19/19	12068
Felicia Horne	7/19/19	30274
Patricia	7/19/19	84790
Evelyn	7/19/19	55443
Minnie	7/19/19	30120
Deasy, Joellen	7/19/19	15035
Susan Field	7/19/19	21030
Susan Field	7/19/19	21030
Amber Vandermolen-Ha	7/19/19	49506
Neyer, John	7/19/19	90503
Wilder, Karen	7/19/19	48602
Kim	7/19/19	48091
Juanzia Dewalt	7/19/19	28217



Cindi McCormick	7/19/19	43731
Prudence	7/19/19	34205
Jeannette L Smith	7/19/19	32413
Jenny	7/19/19	25425
Kimberly	7/19/19	8086
Jana Potter	7/19/19	97217
Frank	7/19/19	18447
Judy	7/19/19	44319
Carol	7/19/19	24018
Patti	7/19/19	95962
Cipra Nemeth	7/20/19	90048
Barry Stuart	7/20/19	53202
William	7/20/19	67211
John L Schaar Sr	7/20/19	81152
R	7/20/19	92567
Janine	7/20/19	8330
John McGregor	7/20/19	32080
Lynne	7/20/19	14456
Gaines, Dorothy	7/20/19	28269
Gallagher, Lynn	7/20/19	95062
Tina Parlato	7/20/19	11518
Lydia	7/20/19	60643
Dana	7/20/19	56073
Isabel	7/20/19	94531
Pam	7/20/19	58701
Walsh, Michael	7/20/19	76206

Godin, Kate	7/20/19	32034
Wigginton, Mark	7/20/19	32034
Stephanie	7/20/19	99701
Alison	7/20/19	52806
John A.	7/20/19	93103
Margaret	7/20/19	68123
Miele, Danielle	7/20/19	01845-1308
Caitlin	7/20/19	44260
Margie	7/20/19	34205
Yvonne	7/20/19	21018
Delores	7/20/19	20171
Elizabeth	7/20/19	50501
Elisabeth Ellenbogen	7/20/19	17109
Alice Nelson	7/20/19	63122
Anderson, Edna	7/20/19	53511
Yvonne	7/20/19	27104
Lenisha	7/20/19	90302
Mike	7/20/19	98528
Susie Folks	7/20/19	19465
Cynthia	7/20/19	33624
Sharen	7/20/19	99654
Janis	7/20/19	97408
Richard	7/20/19	98002
Tammy	7/20/19	25701
Lois	7/20/19	88081
Susan Engle	7/20/19	95351
Michele	7/20/19	53404
Yetive	7/21/19	84737

Vikki	7/21/19	95472
Cindy	7/21/19	34232
Rebecca	7/21/19	89104
Virginia	7/21/19	31805
Carolyn	7/21/19	45223
Robert	7/21/19	66614
Tom	7/21/19	13083
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Teresa Smith-Dixon	7/21/19	97850
Dannye	7/21/19	38059
Claire	7/21/19	22554
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Michele	7/21/19	60137
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Elizabeth Bott	7/21/19	70809
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Marilyn	7/21/19	90621
Holli	7/21/19	97128
Barbara	7/21/19	64116
Marian	7/21/19	89183
Beth Ann	7/21/19	28374
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Paige Harrison Rn	7/21/19	10024
Tiffany Grey	7/21/19	17603
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Connie	7/21/19	32408
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Pamela Seitz	7/21/19	55406
Janice	7/22/19	7960
Robert	7/22/19	10457
Mary Jo	7/22/19	61240
Bill	7/22/19	50112
Robert	7/22/19	14424
Carole	7/22/19	97330
Judith	7/22/19	77590
Cathy Kahl	7/22/19	13039
Melissa	7/22/19	34983
Lisa	7/22/19	33410
Julie Milligan	7/22/19	43015
Jeffery A Neu	7/22/19	45255
Christine Borowiak	7/22/19	48313
Kathleen Seltzer	7/22/19	8844

Jennifer	7/22/19	95490
Mary	7/22/19	45805
Shelley	7/22/19	97322
Seldin, David	7/22/19	20723-2050
Arvie	7/22/19	76574
Denise	7/22/19	82009
Penny Herd	7/22/19	49635
Sharon	7/22/19	5701
Anne	7/22/19	46123
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Charlene Chandler	7/22/19	62526
Sheila	7/22/19	28036
Shirley	7/22/19	7034
Madelaine Reis	7/22/19	20016
Victoria	7/22/19	50131
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Anne	7/22/19	32937
Virgil	7/22/19	66208
Terelle	7/22/19	95519
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David	7/22/19	30562
Mark Steele	7/22/19	49001
Mortz-Rogers, Valerie	7/22/19	46901
Mortz-Rogers, Valerie	7/22/19	46901
David K Bailey	7/22/19	97209

Connie Wonder	7/22/19	17050
Patricia A Paulk	7/22/19	79410
Margaret Burr	7/22/19	88011
Julie	7/22/19	54539
Mel Morgan	7/22/19	60476
Carla	7/22/19	63139
Stephanie	7/22/19	2842
Adele Stefanowicz	7/22/19	17846
Pamela	7/22/19	66095
Juanita Clark	7/22/19	33023
Monte, Suezette	7/22/19	24938
Carol Mongiello	7/22/19	8067
Zina	7/22/19	8830
Gloria	7/22/19	34442
Leora	7/22/19	97212
M H.	7/22/19	78231
Derek	7/22/19	43830
Pamela	7/22/19	95409
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Ann	7/22/19	55422
Tabitha Coburn	7/22/19	95350
Patsy	7/22/19	38558
Carol	7/22/19	60714
Ricks-Lankford, Doris	7/22/19	75254
Willie Brice	7/22/19	98022
Maureen	7/23/19	85205

Joseph	7/23/19	53222
Martha Wilson	7/23/19	78070
Debbi	7/23/19	60152
Vera	7/23/19	12748
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Annelissa Gray-Lion	7/23/19	48118
Elizabeth	7/23/19	62650
Carole	7/23/19	43566
Martha King	7/23/19	18017
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Mazie	7/23/19	53704
Tom Ramsay	7/23/19	87505
Marie	7/23/19	46268
Sandra	7/23/19	45231
Yvette	7/23/19	8831
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Kristi	7/23/19	53022
Sharon	7/23/19	98390
Lafayette J Thomas	7/23/19	60428
Alisha Marrow	7/23/19	8542
Dorothy	7/23/19	69348
Fay Peek	7/23/19	75033
Judy	7/23/19	97760
Evan	7/23/19	21009
Laura	7/23/19	53188
Roberta	7/23/19	14065
Roger Matis	7/23/19	27596
Marilyn	7/23/19	45385

Joyce Guinn	7/23/19	29178
Arlene	7/23/19	15147
Phyllis	7/23/19	33511
Sandy Sulzman	7/23/19	85296
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Tanya	7/23/19	91324
Melvin	7/23/19	3455
Marie	7/23/19	95307
Ginny	7/23/19	2176
Kathy	7/23/19	1106
Lauren	7/23/19	63123
Eloise	7/24/19	61401
Bart	7/24/19	95326
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Charles	7/24/19	2904
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Melissa	7/24/19	5738
A.J	7/24/19	60429
Elsa	7/24/19	44118
Linda	7/24/19	92649
Rainsford	7/24/19	98034



Brittany Chaney	7/24/19	32210
Robin	7/24/19	93510
Conagra Banks	7/24/19	32244
Shirley	7/24/19	76513
Linda	7/24/19	60473
Brenda	7/24/19	33604
Donna	7/24/19	3264
Enrica Byrd	7/24/19	32210
Ericka	7/24/19	23666
Victoria	7/24/19	84121
Carol Sue	7/24/19	30576
Andrea	7/24/19	44708
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Linda	7/24/19	64012
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Ann	7/24/19	44136
Theresa Benfield	7/24/19	34786
Katie	7/24/19	60005
Tina Jones	7/24/19	32277
Beryl	7/24/19	1844
Carolyn	7/24/19	35178
Glorianne Leck	7/24/19	47404
Karen	7/24/19	75901
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Kristen	7/24/19	13219
Dorothy	7/24/19	69348

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Leslie	7/24/19	61265
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Dawn Allen	7/25/19	8203
Regina Stapleslock	7/25/19	75160
Calvin Christensen	7/25/19	84302
Geraldine	7/25/19	83301
Lois Pegg	7/25/19	98611
Coolidge, Anita	7/25/19	92007
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Sarah	7/25/19	28805
Carole	7/25/19	34476
Margaret	7/25/19	22101
Cora	7/25/19	14605
Jordan	7/25/19	70471
Vest, Narcissa	7/25/19	40356
Lynn	7/25/19	97086
John	7/25/19	62573
Kathi	7/25/19	95336
Janet	7/25/19	44111
Marie	7/25/19	46268
Jasmin Robinson	7/25/19	2150
Jacquelyn Korchowsky	7/25/19	14221
Holly Jordan	7/25/19	36265
Dorothy Rissel	7/25/19	86005
Lisa	7/25/19	1529

Patricia	7/25/19	92262
Stacey	7/25/19	97914
Yvonne	7/25/19	46224
Millie Hsrmon	7/25/19	97306
Eldridge, Deborah	7/26/19	34452
M. Lott	7/26/19	77070
Branch, Tammy	7/28/19	75149
Dylan Poore	7/28/19	11706

---

**From:** Frisbie, Suzanne (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C402740CEAAD4D4F97A8C28F16FBB349-FRISBIES]  
**Sent:** 6/19/2018 7:09:32 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Thurston, Kelly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66efcd61b7f84b089ffe2b566b4e135a-thurstonkk]  
**Subject:** FW: KEI License  
**Attachments:** FW: Prospective Grant of Exclusive Patent Commercialization License: Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and Infection  
**Location:** 6C100  
**Start:** 6/27/2018 5:00:00 PM  
**End:** 6/27/2018 5:30:00 PM  
**Show Time As:** Tentative

Hi Mark,

NIAID recently published the following Federal Register Notice for an Intent to Grant an Exclusive:

<https://www.federalregister.gov/documents/2018/06/15/2018-12838/prospective-grant-of-exclusive-patent-commercialization-license-streptococcus-pneumonia-psaa-peptide>

KEI responded with the attached. We were wondering if you would be willing to discuss a proposed response with us. Kelly Thurston, our new Admin. Assistant, has set up a meeting invite currently for June 27<sup>th</sup>. If this is not convenient, please let us know.

Thank you in advance for your advice!

Suzanne

-----Original Appointment-----

**From:** Mowatt, Michael (NIH/NIAID) [E]  
**Sent:** Tuesday, June 19, 2018 2:28 PM  
**To:** Mowatt, Michael (NIH/NIAID) [E]; Frisbie, Suzanne (NIH/NIAID) [E]; Sayyid, Fatima (NIH/NIAID) [E]; Kirby, Tara (NIH/NIAID) [E]; Surabian, Karen (NIH/NIAID) [E]; Rohrbaugh, Mark (NIH/OD) [E]  
**Subject:** KEI License  
**When:** Wednesday, June 27, 2018 1:00 PM-1:30 PM (UTC-05:00) Eastern Time (US & Canada).  
**Where:** 6C100

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Request by Karen

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**From:** Surabian, Karen (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=604A0E2013504631921434A90B327010-SURABIANK\_1]  
**Sent:** 6/18/2018 3:57:45 PM  
**To:** Frisbie, Suzanne (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c402740ceaad4d4f97a8c28f16fbb349-frisbies]  
**CC:** Kirby, Tara (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2368a591fa4c4932a802e5d467fb49ed-tarak]; Sayyid, Fatima (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b9e45041bdb43719f7113a5aae27057-sayyidf]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]  
**Subject:** FW: Prospective Grant of Exclusive Patent Commercialization License: Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and Infection  
**Flag:** Follow up

-----  
Karen T. Surabian  
Licensing and Patenting Manager  
CDC Team  
Technology Transfer and Intellectual Property Office (TTIPO)  
National Institute of Allergy and Infectious Diseases (NIAID)  
National Institutes of Health (NIH)  
5601 Fishers Lane, Rm. 2G48, MSC 9804  
Rockville, MD 20892

Phone: [+1-301-594-9719](tel:+1-301-594-9719)  
Email: [karen.surabian@nih.gov](mailto:karen.surabian@nih.gov)

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**From:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>  
**Sent:** Monday, June 18, 2018 5:17 AM  
**To:** Surabian, Karen (NIH/NIAID) [E] <[karen.surabian@nih.gov](mailto:karen.surabian@nih.gov)>  
**Cc:** Manon Ress <[manon.ress@keionline.org](mailto:manon.ress@keionline.org)>; Luis Gil Abinader <[luis.gil.abinader@keionline.org](mailto:luis.gil.abinader@keionline.org)>  
**Subject:** Re: Prospective Grant of Exclusive Patent Commercialization License: Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and Infection

While we wait for answers to the questions asked, KEI can offer initial comments on the license.

1. We object to granting exclusive rights in any country with per capita income less than 30 percent of U.S per capita income, as measured by the World Bank Atlas method. We don't think the incentive provided by extending the license to the lower income countries is significant, and we think the negative impact on access is significant.

2. We suggest NIAID reserve an option to provide the Medicines Patent Pool rights to license to the invention to generic manufacturers in all countries with per capita income less than 30 percent of U.S. per capita income.
3. KEI suggests the initial period of exclusivity is set at seven years, subject to extensions if the company can demonstrate it has not recovered sufficient profits given the risk-adjusted value of the clinical trials used to register similar drugs for the lead indication. Absent a shorter license term, we propose the exclusivity of the product be reduced when cumulative global revenues for the product exceed \$1 billion, by one year for every \$0.5 billion in cumulative sales that exceed \$1 billion in cumulative sales. The NIH might consider a different set of benchmarks than \$1 billion and \$.5 billion. In considering any benchmarks for global sales benchmarks, note that the licensing of inventions to the company significantly reduces the company's costs of preclinical research, which various studies have estimated to be 40 to 55 percent of drug development costs on a risk- and capital cost-adjusted basis.
4. To prevent discrimination against US resident, products based upon the licensed patents should be priced no higher in the United States than the median price charged in the seven largest economies as measured by nominal GNI that have a nominal GNI per capita of at least 50 percent of the United States. To fully appreciate our concerns about the discriminatory pricing that makes US residents pay more than everyone else, please review the cross country price comparisons here: <http://drugdatabase.info/drug-prices/>
5. Prices for products in the United States should also not exceed the estimated value of the treatment, as determined by independent health technology assessments selected by Department of Health and Human Services (HHS).
6. To address transparency, we proposes the company be required to provide an annual report for the public providing disclosures of the following items:
  - a. The amount of money R&D to obtain FDA and foreign government approvals of the inventions, including in particular, the amount of money spent each year on each trial, and the relevant tax credits, grants and other subsidies received from any government or charity relating to those R&D outlays,
  - b. The prices and revenue for the products, by country,
  - c. The number of units sold, in each country,
  - d. The product-relevant patents obtained in each country, and
  - e. The regulatory approval obtained in each country.

On Mon, Jun 18, 2018 at 10:48 AM, James Love <[james.love@keionline.org](mailto:james.love@keionline.org)> wrote:

Karen Surabian,  
Licensing and Patenting Manager,  
Technology Transfer and Intellectual Property Office,  
National Institute of Allergy and Infectious Diseases,  
5601 Fishers Lane, Suite 6D, MSC9804, Rockville, MD 20852-9804,  
phone number 301-496-2644  
[karen.surabian@nih.gov](mailto:karen.surabian@nih.gov)

RE:

Prospective Grant of Exclusive Patent Commercialization License: Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and Infection

Dear Karen Surabian,

I have a few questions about this license.

1. What is the proposed royalty and other consideration?
2. Has the NIAID undertake an economic analysis of term of the license that is necessary, given the limits on the scope of rights for exclusive license in 35 USC 209?
3. Will the invention be manufactured in the United States?
4. Where will the research and development be performed?
5. Are any former NIH employees involved in the license?
6. Has NIAID requested DOJ to revenue the license, under 40 USC 559?

James Love  
Knowledge Ecology International

--  
James Love, Knowledge Ecology International

<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, [twitter.com/jamie\\_love](https://twitter.com/jamie_love)

--  
James Love, Knowledge Ecology International

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**From:** Berkley, Dale (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/CN=OD/CN=BERKLEYD]  
**Sent:** 6/6/2017 1:34:20 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/cn=OD/cn=ROHRBAUM]; Lambert, Richard (NIH/NIAID) [C] [/O=NIH/OU=NIH/EXCHANGE/cn=NIAID/cn=LAMBERTR]; Mowatt, Michael (NIH/NIAID) [E] [/O=NIH/OU=NIH/EXCHANGE/cn=NIAID/cn=MMOWATT]  
**Subject:** RE: [Ip-health] KEI asks the Department of Health and Human Services to adopt a policy on licensing CRISPR patents

b5

b5

Check with Susan Rucker on this.

Dale

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
301-496-6043  
301-402-2528(Fax)

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-----Original Message-----

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Tuesday, June 06, 2017 9:11 AM  
**To:** Lambert, Richard (NIH/NIAID) [C] <lambertr@niaid.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>; Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>  
**Subject:** RE: [Ip-health] KEI asks the Department of Health and Human Services to adopt a policy on licensing CRISPR patents

b5

-----Original Message-----

**From:** Lambert, Richard (NIH/NIAID) [C]  
**Sent:** Tuesday, June 06, 2017 7:52 AM  
**To:** Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>  
**Subject:** FW: [Ip-health] KEI asks the Department of Health and Human Services to adopt a policy on licensing CRISPR patents

FYI

Richard A. Lambert  
Contractor  
National Institute of Allergy and Infectious Diseases National Institutes of Health U.S. Department of Health and Human Services  
5601 Fishers Lane, Rm. 2G47, MSC 9804  
Bethesda, MD 20892-9804  
(Courier: Rockville, MD. 20852)  
301.496.2644 main officeline  
240.627.3706 direct line  
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lambertr@niaid.nih.gov

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-----Original Message-----

**From:** Jamie Love [mailto:james.love@keionline.org]  
**Sent:** Tuesday, June 06, 2017 7:43 AM  
**To:** Ip-health <ip-health@lists.keionline.org>  
**Cc:** Diane Singhroy <diane.singhroy@keionline.org>; Andrew S. Goldman <andrew.goldman@keionline.org>  
**Subject:** [Ip-health] KEI asks the Department of Health and Human Services to adopt a policy on licensing CRISPR patents

<http://keionline.org/node/2801>

KEI asks the Department of Health and Human Services to adopt a policy on licensing CRISPR patents 6.  
June 2017 - 5:21

REL0000023908

On June 6, 2017, Knowledge Ecology International wrote to the U.S. Department of Health and Human Services (DHHS) asking the Department to adopt a policy on the licensing of federally-funded CRISPR patented inventions. (Copy here).

<http://keionline.org/sites/default/files/CRISPR-SecPrice-6Jan2017.pdf>

In part 1, the 17 page letter reviews the importance of the CRISPR technology. Part 2 discusses the public interest in non-discriminatory licensing of CRISPR patent. In part 3, makes suggestions regarding the policies that would advance the public interest, and ensure that those inventions are "available to the public on reasonable terms" and that the licenses are designed to achieve the purposes and objectives of the Bayh-Dole Act and to maximize the benefits to taxpayers and patients.

The table of contents of the letter is as follows:

-----  
Table of contents

Part 1. The CRISPR technology has important research and medical applications.  
Figure 1: Pipeline of CRISPR-Cas- assisted drug discovery (From Fellmann C et al.)

Part 2. There is a public interest in open, non-discriminatory licensing of CRISPR patents on reasonable terms.

1. The CRISPR patent landscape and licensing arrangements Table 1: CRISPR patent landscape Figure 2: CRISPR-CAS9 licensing agreements

2. Exclusive licenses on CRISPR are contrary to federal guidance

3. Exclusive licenses are an unnecessary and inappropriate means to incentivize research using the CRISPR platform.

4. Exclusive licenses on CRISPR patents will limit patient access.

Part 3. DHHS policy on the licensing of CRISPR patents.

Conclusion

Annex 1: NIH Sharing Policies and Related Guidance  
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The suggestions on licensing are as follows:

Part 3. DHHS policy on the licensing of CRISPR patents.

As noted in Annex 1, DHHS has adopted at least 20 statements on sharing policies and related guidance for NIH-funded research resources.

There is a pressing need for a U.S. government policy statement regarding the licensing of government-funded CRISPR inventions.

The following comments are offered to assist the DHHS in developing such a policy statement:

1. In 2001 and in subsequent agreements with the WiCell Research Institute, Inc., the NIH intervened to ensure access to non-commercial research institutions to patented inventions involving stem cells.[fn [48]] The WiCell/NIH agreement can be seen as implementing a 1999 NIH policy statement on "Sharing Biomedical Research Resources,"[fn [49]] and focused primarily on ensuring non-profit entities would be able to use stem cells for research purposes.[fn [50]]

2. The policy statement for CRISPR patents should ensure non-exclusive licensing in all fields of technology. The CRISPR technology is not a product, but a tool that can be used to create products and advance our understanding of human diseases. It is in the public interest to ensure non-discriminatory freedom to use the technology, in some cases royalty-free, and in other cases with fair and reasonable remuneration.

3. A related area concerns patents that are essential to implement standards. For many technologies, including but not limited to those involving networked information technologies or green energy technologies, so-called standards essential patents (SEPs) can impose costs on society and limit innovation, if licensed on unreasonable or discriminatory terms. Often these disputes are resolved through contracts between patent holders and Standards Developing Organizations (SDOs), with a commitment that the patent holders agree to license patents on fair, reasonable, and non-discriminatory terms, referred to as FRAND terms. The US Patent and Trademark Office (USPTO) and the U.S. Department of Justice (USDODJ) have addressed this issue in a nuanced January 8, 2013 policy statement.[fn [51]]

4. In the case of the CRISPR patents, the policy should be to ensure open and non-discriminatory licensing of the patents to both nonprofit and for-profit entities.

5. The licensing of CRISPR patents to non-commercial entities for research purposes should be royalty-free, a condition met by earlier CRISPR patent holders.
6. The licensing of CRISPR patents to commercial entities may require payment of royalties, but only on FRAND terms.
7. The licensing of CRISPR patents to any entity should not have reach-through rights to subsequent patents, unless the reach-through clause is designed to benefit an entity that is creating a research commons.
8. The funding agency should require the patent holders to disclose license agreements and royalty payments, as well as the rationale for royalties charged.
9. The NIH should reserve the right to require that royalty payments be based upon only the use as a research tool, or only on final products.

. . .

#### Notes

[48] WiCell Agreement No. 02-W012B, 09042012 NIH, Amended and Restated Memorandum of Understanding between WiCell Research Institute, Inc. and Public Health Service U.S. Department of Health and Human Services.

November 2012.

<https://www.ott.nih.gov/sites/default/files/documents/pdfs/wicell-rev.pdf>

[49] National Institutes of Health. Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts. Federal Register Vol. 64, No. 246, page 72090-6. December 23, 1999.

[50] Debra Robertson, NIH sacrifices commercial rights in WiCell deal, Nature Biotechnology 19, 1001 (1 November 2001), doi:10.1038/nbt1101-1001.

[51] United States Department Of Justice And United States Patent & Trademark Office Policy Statement On Remedies For Standards-essential Patents Subject To Voluntary F/rand Commitments January 8, 2013

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James Love. Knowledge Ecology International <http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile:

+41.76.413.6584, [twitter.com/jamie\\_love](https://twitter.com/jamie_love)

---

Ip-health mailing list

[ip-health@lists.keionline.org](mailto:ip-health@lists.keionline.org)

[http://lists.keionline.org/mailman/listinfo/ip-health\\_lists.keionline.org](http://lists.keionline.org/mailman/listinfo/ip-health_lists.keionline.org)

---

**From:** Baker, Rebecca (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BAKERRG]  
**Sent:** 11/7/2016 5:22:25 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/cn=OD/cn=ROHRBAUM]  
**CC:** Wolinetz, Carrie (NIH/OD) [E] [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Wolinetzcdc9a]; Schulke, Hilda (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/cn=OD/cn=schulkeh]  
**Subject:** Re: time sensitive request: talking points for today's xtandi meeting

Thanks!!

Sent from my iPhone

On Nov 7, 2016, at 11:26 AM, Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV> wrote:

**From:** Baker, Rebecca (NIH/OD) [E]  
**Sent:** Monday, November 07, 2016 11:13 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>  
**Cc:** Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>  
**Subject:** RE: time sensitive request: talking points for today's xtandi meeting

Thanks Mark.

This is a great background.

Could you also please

b5

Thanks,  
Rebecca

---

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Monday, November 7, 2016 11:07 AM  
**To:** Baker, Rebecca (NIH/OD) [E] <bakerrg@od.nih.gov>  
**Cc:** Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>  
**Subject:** RE: time sensitive request: talking points for today's xtandi meeting

Is this look like what you/ KH wants?

**From:** Baker, Rebecca (NIH/OD) [E]  
**Sent:** Monday, November 07, 2016 9:19 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>  
**Cc:** Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>  
**Subject:** time sensitive request: talking points for today's xtandi meeting

Hi Mark,

Update on today's meeting with KEI:

Barb won't be joining and it will be just you, me, and Kathy.

b5

REL0000023910

**b5**

Thanks,  
Rebecca

<Xtandi KEI government use license.docx>

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**From:** Dodson, Sara (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=985A956EAA0D4945BDCFD8EA30947D68-DODSONSE]  
**Sent:** 12/1/2017 6:36:55 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Koniges, Ursula (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d5ae2c3139654bc0b9b95718d516310b-konigesum]  
**Subject:** RE: Drug pricing

**b5**

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Friday, December 01, 2017 12:31 PM  
**To:** Dodson, Sara (NIH/OD) [E] <sara.dodson@nih.gov>  
**Cc:** Koniges, Ursula (NIH/OD) [E] <ursula.koniges@nih.gov>  
**Subject:** Drug pricing

Earlier this year, KEI sent letter to HHS and cc FC requesting action to stop exclusive licensing of CRISPR under policy considerations such as Research Tools Guidelines.

**b5**

**b5**

Mark L. Rohrbaugh, Ph.D., J.D.  
Special Advisor for Technology Transfer  
Director, Division of Technology Transfer and Innovation Policy  
Office of Science Policy  
Office of the Director  
National Institutes of Health

---

**From:** Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=HAMMERSLAA]  
**Sent:** 5/4/2017 3:08:14 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]  
**Subject:** FW: royalties

Added more below (highlighted) : Also your number again is .....? Mine is

b6

**From:** Hammersla, Ann (NIH/OD) [E]  
**Sent:** Thursday, May 04, 2017 10:53 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>  
**Subject:** FW: royalties

Mark:: A start:

b5

**b5**

**From:** Hammersla, Ann (NIH/OD) [E]  
**Sent:** Thursday, May 04, 2017 10:08 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[RohrBauM@OD.NIH.GOV](mailto:RohrBauM@OD.NIH.GOV)>  
**Subject:** FW: royalties

I think that we can also use some language

**b5**

**b5**



**b5**

**From:** Hammersla, Ann (NIH/OD) [E]  
**Sent:** Thursday, May 04, 2017 9:57 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[RohrBauM@OD.NIH.GOV](mailto:RohrBauM@OD.NIH.GOV)>  
**Subject:** RE: royalties

Good Morning: I am just pulling up the OGC comments.

**b5**

**b5**

**b5**

If you would like to draft I am on-line for most of the morning. Ann

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Thursday, May 04, 2017 9:47 AM  
**To:** Hammersla, Ann (NIH/OD) [E] <[hammerslaa@mail.nih.gov](mailto:hammerslaa@mail.nih.gov)>  
**Subject:** Re: royalties

The revised KEI letter is due today. If I take a stab at it, are you able to look it over today?

Sent from my iPhone

REL0000023912

On May 4, 2017, at 9:32 AM, Hammersla, Ann (NIH/OD) [E] <[hammerslaa@mail.nih.gov](mailto:hammerslaa@mail.nih.gov)> wrote:

Good Morning: Thanks Mark for adding the additional information. I am at the NIH Regional meeting and yesterday was a workshop on IP.

Ann

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Wednesday, May 03, 2017 4:36 PM  
**To:** Tabak, Lawrence (NIH/OD) [E] <[Lawrence.Tabak@nih.gov](mailto:Lawrence.Tabak@nih.gov)>  
**Cc:** Wolinetz, Carrie (NIH/OD) [E] <[carrie.wolinetz@nih.gov](mailto:carrie.wolinetz@nih.gov)>; Hammersla, Ann (NIH/OD) [E] <[hammerslaa@mail.nih.gov](mailto:hammerslaa@mail.nih.gov)>  
**Subject:** RE: royalties

I believe Ann is on official travel. Here is my revision.

**From:** Tabak, Lawrence (NIH/OD) [E]  
**Sent:** Wednesday, May 03, 2017 2:33 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[RohrBauM@OD.NIH.GOV](mailto:RohrBauM@OD.NIH.GOV)>; Hammersla, Ann (NIH/OD) [E] <[hammerslaa@mail.nih.gov](mailto:hammerslaa@mail.nih.gov)>  
**Cc:** Wolinetz, Carrie (NIH/OD) [E] <[carrie.wolinetz@nih.gov](mailto:carrie.wolinetz@nih.gov)>  
**Subject:** royalties  
**Importance:** High

Mark, Ann-

Please see FC comments on your proposal. Could you please address questions/comments and return to me asap?

Thanks  
Larry

**From:** Plude, Denise (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=PARKSDE]  
**Sent:** 5/8/2017 5:07:38 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]  
**Subject:** RE: ES - WF 357204 - Necessary Action (CC)

Since the assignment was in our queue and you sent it, I uploaded in DDRMs. Please let me know if that's not what you wanted and we need to contact Exec Sec.

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Monday, May 08, 2017 1:06 PM  
**To:** Plude, Denise (NIH/OD) [E] <pludedede@mail.nih.gov>  
**Subject:** Re: ES - WF 357204 - Necessary Action (CC)

I am confused because what I sent was OER's request to their ES person to upload it

Sent from my iPhone

On May 8, 2017, at 12:46 PM, Plude, Denise (NIH/OD) [E] <pludedede@mail.nih.gov> wrote:

I uploaded what you sent last Thursday. OGC is reviewing that version as far as I know.

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Monday, May 08, 2017 12:42 PM  
**To:** Plude, Denise (NIH/OD) [E] <[pludedede@mail.nih.gov](mailto:pludedede@mail.nih.gov)>  
**Subject:** Re: ES - WF 357204 - Necessary Action (CC)

I did not approve the last "final". OER modified it based on comments and I was not given the chance to review these changes before they uploaded it.

Sent from my iPhone

On May 8, 2017, at 12:01 PM, Plude, Denise (NIH/OD) [E] <pludedede@mail.nih.gov> wrote:

**From:** Hurlebaus, Lisa (NIH/OD) [E]  
**Sent:** Monday, May 08, 2017 11:57 AM  
**To:** Plude, Denise (NIH/OD) [E] <[pludedede@mail.nih.gov](mailto:pludedede@mail.nih.gov)>  
**Subject:** RE: ES - WF 357204 - Necessary Action (CC)

I wasn't planning to send it back to OSP for clearance, unless OGC has more clearance comments. OGC is clearing now and, if they concur, the version wouldn't change from what you sent me on Friday. So, I would send to Dr. Tabak for clearance and Dr. Collins for signature.

Is there a reason OSP needs to see the draft again?

**From:** Plude, Denise (NIH/OD) [E]  
**Sent:** Monday, May 08, 2017 10:46 AM

REL0000023913

**To:** Hurlebaus, Lisa (NIH/OD) [E] <[marshall@od.nih.gov](mailto:marshall@od.nih.gov)>

**Subject:** RE: ES - WF 357204 - Necessary Action (CC)

Hi Lisa, will this come back for another clearance?

**Work Folder Information**

**Work Folder:** WF 357204

**Process:** Necessary Action

**Program Analyst:** Hurlebaus, Lisa (NIH/OD) [E]

**Due Date:** May 04, 2017

**WF Subject:** OS assignment. KEI & UACT write about the prostate cancer drug, Xtandi (enzalutamide). Asks the Government to reconsider the decision not to use the 'march-in' rights, under the Bayh-Dole Act, for this excessively-priced drug. (AS-760889)

**IC:** od\_osp

**From:** Goldman, Andrew

**To:** Price, TomMattis, Jim

**Remarks:** b5

b5

**Additional instructions are included on the task form, click the link to open the Task**

---

**From:** Lambert, Richard (NIH/NIAID) [C] [/O=NIH/OU=NIH/EXCHANGE/CN=NIH/NIAID/CN=LAMBERTR]  
**Sent:** 5/12/2016 12:43:57 PM  
**To:** Rohrbach, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/cn=OD/cn=ROHRBAUM]  
**Subject:** FW: [Ip-health] RAPS: NIH's Exclusive Licenses to Biotech, Pharma Start-Ups: Lots of Secrecy, Few Successes

FYI

Richard A. Lambert  
Contractor  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health  
U.S. Department of Health and Human Services  
5601 Fishers Lane, Rm. 2G47, MSC 9804  
Bethesda, MD 20892-9804  
(Courier: Rockville, MD. 20852)  
301.496.2644 main officeline  
240.627.3706 direct line  
FAX 240.627.3117  
lambertr@niaid.nih.gov

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-----Original Message-----

From: Michael H Davis [mailto:m.davis@csuohio.edu]  
Sent: Wednesday, May 11, 2016 5:58 PM  
To: Zack Struver; ip-health@lists.keionline.org  
Subject: Re: [Ip-health] RAPS: NIH's Exclusive Licenses to Biotech, Pharma Start-Ups: Lots of Secrecy, Few Successes

This is rather interesting. The NIH and fda refuse to judge the reasonableness of prices with the excuse that they don't have expertise in such matters. But they do have expertise to judge whether documents deserve confidentiality or not. How do they get to choose their areas of expertise? Apparently when it suits them.

Sent from my T-Mobile 4G LTE Device

----- Original message -----

From: Zack Struver <zack.struver@keionline.org>  
Date: 11/05/2016 15:35 (GMT-05:00)  
To: ip-health@lists.keionline.org  
Subject: [Ip-health] RAPS: NIH's Exclusive Licenses to Biotech, Pharma Start-Ups: Lots of Secrecy, Few Successes

<http://www.raps.org/Regulatory-Focus/News/2016/05/10/24906/NIH%E2%80%99s-Exclusive-Licenses-to-Biotech-Pharma-Start-Ups-Lots-of-Secrecy-Few-Successes/>

NIH's Exclusive Licenses to Biotech, Pharma Start-Ups: Lots of Secrecy, Few Successes

Posted 10 May 2016

By Zachary Brennan

It's well-known that the National Institutes of Health (NIH) offers billions of dollars in grants to US academic research facilities. What's less well-known is that each year, hundreds of new inventions are produced in the laboratories of NIH, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), and these inventions are licensed out to private companies in the US and internationally for further research and development, with the hopes of bringing new products to market.

The licenses generate significant amounts of revenue for NIH. From 1988 to

REL0000023914

2004, NIH entered into almost 2,500 license agreements and generated more than \$500 million in royalty revenues, according to a study from Nature Biotechnology.

And among those licensing opportunities, there's a subset of exclusive licenses, meaning the use of the invention is limited to the license holder, which are offered to only tiny start-up biotech, pharmaceutical and medical device companies that are less than five years old, have raised less than \$5 million and have less than 50 employees.

.....

#### Transparency Questions

More recently, NIH has awarded exclusive licenses to companies that don't have office space or even websites.

James Love, director of the non-profit non-governmental organization Knowledge Ecology International, which has been denied information from NIH on the exclusive licenses, told Focus: "I think the NIH is operating in a highly non-transparent manner, really appalling. Nothing that is not in the federal register notice is known about the licenses. They won't answer questions about the state of the technology, provide copies of the patent applications, give out the addresses or names of principals the businesses that have no web pages. They won't give the royalty rate, the term of the license, or answer any questions about the analysis that was done to limit the exclusivity to something less than worldwide life of patent rights.

The NIH seems to be ignoring the requirements of 35 USC 209(a)(1-2)."

For instance, NIH released a proposal to grant exclusive patent licenses to Vital Spark Inc. and Kalytera Therapeutics Inc. for CB1 receptor mediating compounds, but as KEI noted, Vital Spark does not have a website and there's "virtually no information" on their status as a company.

"As far as we know, the NIH has not demonstrated why granting an exclusive license to either company is necessary, how the proposed scope of exclusivity is limited to that "reasonably necessary to provide the incentive for bringing the invention to practical application," or how the NIH will ensure that the inventions is available to the public on reasonable terms, including but not limited to a reasonable price," KEI said in a letter to NIH on 4 May.

Last year, NIH granted a start-up exclusive commercial patent license to Virotas Biopharmaceuticals, which also does not have a website and is listed as an LLC based in Delaware, though NIH said the company is based in California.

Sudarshan Upadhy, co-founder and chief scientific officer of AestasRx, which does not have a website but won the exclusive start-up license to develop diagnostics for Alzheimer's and other diseases, told Focus that he could not discuss his work because of a non-disclosure agreement with NIH.

Ram Aiyar, executive vice president of corporate and business development at Corvidia, which has four employees and was granted an exclusive NIH start-up license this year for a cardiovascular therapeutic, told Focus his company is targeting certain segments of cardiovascular disease with mortality rates higher than 20%.

He said the company's decision to apply for the license was based on Corvidia CEO Michael Davidson's relationship with an NIH official, though the company was not launched "solely based off of that asset." Corvidia recently closed \$26 million in Series A financing, though Aiyar declined to offer any details on the timeline for the development of the NIH-developed therapeutic.

Sai Prashant Boyreddy, manager of Great Lakes Neuroscience, told Focus, noting his start-up of seven employees is still working on obtaining an exclusive license from NIH, which is reviewing the company's comments. He said NIH's due diligence has been a "long and lengthy process" and that he should know in two or three weeks if they've won the license. If they do,



he said the company could hire more employees.

"The most important thing that needs to be told is that these inventions cannot be commercialized by NIH," Boyreddy said. "And the inventions are at such an early stage that large pharmaceutical companies don't want to waste their time on them."

An NIH spokeswoman also told Focus: "Any information about why a company submitting an application for an exclusive license was found acceptable would be business confidential and not subject to release to the public."

--

Zack Struver, Communications and Research Associate  
Knowledge Ecology International  
zack.struver@keionline.org  
Twitter: @zstruver <<https://twitter.com/zstruver>>  
Office: +1 (202) 332-2670 Cell: +1 (914) 582-1428  
keionline.org

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Ip-health mailing list  
Ip-health@lists.keionline.org  
[http://lists.keionline.org/mailman/listinfo/ip-health\\_lists.keionline.org](http://lists.keionline.org/mailman/listinfo/ip-health_lists.keionline.org)

---

Ip-health mailing list  
Ip-health@lists.keionline.org  
[http://lists.keionline.org/mailman/listinfo/ip-health\\_lists.keionline.org](http://lists.keionline.org/mailman/listinfo/ip-health_lists.keionline.org)

---

**From:** Freel, Rose (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E8AE9AAB7E3249E881BB573E9A189036-FREELRM]  
**Sent:** 7/2/2018 1:30:53 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]  
**Subject:** RE: 83 FR 30448, Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

Hi Mark,

Looking forward to speaking with you at 2 today.

b5

Thanks!

Rose

--

Rose Santangelo Freel, Ph.D.  
Technology Transfer Manager  
**National Cancer Institute**  
P 301-624-1257 | [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Friday, June 29, 2018 11:08 AM  
**To:** Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>  
**Subject:** RE: 83 FR 30448, Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

I spoke with Dale and

b5

b5

**From:** Freel, Rose (NIH/NCI) [E]  
**Sent:** Friday, June 29, 2018 9:26 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[RohrBauM@OD.NIH.GOV](mailto:RohrBauM@OD.NIH.GOV)>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>  
**Subject:** FW: 83 FR 30448, Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

Hi Mark,

See email below from KEI regarding a FR Notice for intent to grant. Let me know when you have time to discuss.

Thanks!

Rose

--

Rose Santangelo Freel, Ph.D.  
Technology Transfer Manager  
**National Cancer Institute**

REL0000023915



P 301-624-1257 | [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

**From:** James Love [<mailto:james.love@keionline.org>]

**Sent:** Thursday, June 28, 2018 4:04 PM

**To:** Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)>

**Cc:** Claire Cassedy <[claire.cassedy@keionline.org](mailto:claire.cassedy@keionline.org)>

**Subject:** 83 FR 30448, Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

Rose M. Freel, Ph.D.,  
Licensing and Patenting Manager,  
NCI Technology Transfer Center,  
8490 Progress Drive, Suite 400, Frederick, MD 21701;  
Email: [rose.freel@nih.gov](mailto:rose.freel@nih.gov).

Dear Dr  
Freel,

Has the technology referred to in 83 FR 30448, regarding Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer, been subject to any clinical trials (1) funded by the NIH, or (2) funded by any other party?

This information is useful for KEI in preparing our comments on the license.

Jamie

--

James Love. Knowledge Ecology International

<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, [twitter.com/jamie\\_love](https://twitter.com/jamie_love)

REL0000023915

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**From:** Joe Allen [jallen@allen-assoc.com]  
**Sent:** 9/19/2017 2:34:19 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Hammersla, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87fb28aa23744c0b855ef0683ac2e8b4-hammerslaa]  
**Subject:** My Power point for Oct 12 presentation to NIH  
**Attachments:** Presentation to NIH Oct 2017.pptx

FYI

--

Joseph P. Allen  
President  
Allen and Associates  
60704 Rt. 26, South  
Bethesda, OH 43719  
(W) 740-484-1814  
(C) [REDACTED] b5  
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**b4**



**b4**

**b4**

**b4**

**b4**

**b4**

**b4**

---

**From:** Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]  
**Sent:** 6/14/2018 5:24:28 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Seigfreid, Kim (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=918ccb3c48ea40e79a0ab243e5d35298-seigfreidks]  
**CC:** Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]  
**Subject:** RE: Worth responding to? NIH CRADA

Hi Mark:

Thanks for dropping in; see below and let us know if this looks okay.

b5

**From:** Myles, Renate (NIH/OD) [E]  
**Sent:** Wednesday, June 13, 2018 4:42 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Seigfreid, Kim (NIH/OD) [E] <kimberly.seigfreid@nih.gov>  
**Cc:** Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>  
**Subject:** RE: Worth responding to? NIH CRADA

b5

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Wednesday, June 13, 2018 4:08 PM  
**To:** Seigfreid, Kim (NIH/OD) [E] <kimberly.seigfreid@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>  
**Cc:** Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>  
**Subject:** RE: Worth responding to? NIH CRADA

I will be taking to NCI about their approach, just to confirm. I think we should talk about this. I think it is a little more nuanced.

**From:** Seigfreid, Kim (NIH/OD) [E]  
**Sent:** Wednesday, June 13, 2018 3:54 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>  
**Cc:** Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>  
**Subject:** RE: Worth responding to? NIH CRADA

Would something like this be a fair response? I pulled an example from 2018 to be more current.

b5

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Wednesday, June 13, 2018 3:20 PM  
**To:** Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>  
**Cc:** Seigfreid, Kim (NIH/OD) [E] <kimberly.seigfreid@nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>;  
Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>  
**Subject:** RE: Worth responding to? NIH CRADA

The NIH Policy Chapter says:

**b5**

**From:** Myles, Renate (NIH/OD) [E]  
**Sent:** Wednesday, June 13, 2018 2:22 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>  
**Cc:** Seigfreid, Kim (NIH/OD) [E] <kimberly.seigfreid@nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>;  
Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>  
**Subject:** RE: Worth responding to? NIH CRADA

**b5**

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Wednesday, June 13, 2018 2:14 PM  
**To:** Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>  
**Cc:** Seigfreid, Kim (NIH/OD) [E] <kimberly.seigfreid@nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>;  
Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>  
**Subject:** RE: Worth responding to? NIH CRADA

I don't know

**b5**

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Tuesday, June 12, 2018 5:30 PM  
**To:** Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>  
**Cc:** Seigfreid, Kim (NIH/OD) [E] <kimberly.seigfreid@nih.gov>; Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>;  
Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>  
**Subject:** Re: Worth responding to? NIH CRADA

**b5**



# b5

Sent from my iPhone

On Jun 12, 2018, at 4:51 PM, Myles, Renate (NIH/OD) [E] <[mylesr@mail.nih.gov](mailto:mylesr@mail.nih.gov)> wrote:

Looping in Mark Rohrbaugh. Mark: do you know what Jamie Love is getting at here?

**From:** Seigfreid, Kim (NIH/OD) [E]  
**Sent:** Tuesday, June 12, 2018 4:20 PM  
**To:** Myles, Renate (NIH/OD) [E] <[mylesr@mail.nih.gov](mailto:mylesr@mail.nih.gov)>  
**Subject:** Worth responding to? NIH CRADA

Hi Renate,

b5

[https://twitter.com/jamie\\_love/status/1006496361141940224](https://twitter.com/jamie_love/status/1006496361141940224)

**James Love** Verified account **@jamie\_love**: Not sure if everyone knows, but the **@NIHDirector** has decided that the **@NIH** (unlike the Army, Coast Guard, Homeland Security, or the Dept of Commerce) no longer provides public notices of CRADAs. It's part of Collin's minimal transparency policy for NIH owned IP.

Kim

Kim Seigfreid  
Public Affairs Specialist  
Office of Communications and Public Liaison  
National Institutes of Health  
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ph: 301-435-3639  
fx: 301-496-0017  
[kim.seigfreid@nih.gov](mailto:kim.seigfreid@nih.gov)  
Follow the NIH Director on <image001.png> [Twitter](#) and <image002.png> [Email Updates](#)  
Follow the NIH on <image003.png> [Facebook](#), <image001.png> [Twitter](#), and <image004.png> [YouTube](#)

REL0000023919

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**From:** Joe Allen [jallen@allen-assoc.com]  
**Sent:** 4/24/2019 8:39:28 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Hammersla, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87fb28aa23744c0b855ef0683ac2e8b4-hammerslaa]  
**Subject:** STAT: A Commerce Dept report causes a stir over whether to use federal law to lower drug prices

Here's the next shot (<https://www.statnews.com/pharmalot/2019/04/24/commerce-department-report-drug-prices/>). Note the last sentence that I bolded. Any idea what that's about?

## **A Commerce Department report causes a stir over whether to use federal law to lower drug prices**

By **ED SILVERMAN** @Pharmalot  
APRIL 24, 2019

At the same time the Trump administration has vowed to attack rising drug costs, the Department of Commerce has released a report that some academics and consumer advocates argue would restrain the ability of the federal government to limit “excessive” prescription drug prices.

In a [lengthy document](#) that largely mirrors a [draft report](#) leased late last year, the department’s National Institute of Standards and Technology offers suggestions for modernizing technology transfer and innovation, and proposed several ideas for maximizing returns on taxpayer investment in R&D.

“The purpose is to address U.S. economic competitive and security,” Walter Copan, Under Secretary of Commerce for Standards and Technology Director at NIST, told us. He added that the report is not a policy document, but the basis for further discussion.

“But the federal law should be true to its initial purpose of stimulating entrepreneurship and investment in the economy. Drug pricing is outside the purview of the federal technology transfer mechanisms. There are other tools to address those concerns.”

Nonetheless, consumer groups and academics argue otherwise.

“Walter Copan is more interested in making drug companies happy than protecting the interests of the people who pay his salary,” fumed Jamie Love, who heads Knowledge Ecology International, an advocacy group that tracks access to medicine and patent issues. The report is “a sneak attack on the public interest safeguards” in federal law.

As one example, he pointed to a portion of the NIST report that seeks to narrow the rights the U.S. has under what is called a government use license, which gives the federal government the right to use a patented invention without permission, but pay the patent holder reasonable compensation. Other countries have explored this notion to gain leverage to lower drug prices.

Another topic concerns so-called march-in rights for reclaiming patents as a means to address high prices for prescription medicines. Although highly controversial among drug makers and their supporters, the concept has gained traction over the last few years in response to the national debate about the high cost of medicines. But the report would mitigate its use to combat high drug prices.

Under federal law, a government agency that funds private research — such as the National Institute of Health — can require a drug maker to license its patent to another party in order to “alleviate health and safety needs which are not being reasonably satisfied.” An agency can also do so when the benefits of a product, such as a medicine, are not available on “reasonable terms.”

A growing number of consumer advocates, academics, and lawmakers have argued that medicines invented with taxpayer dollars should be affordable to Americans. Two years ago, for instance, the Senate Armed Services Committee proposed that the Department of Defense use march-in rights when prices in the U.S. were higher than the median price in seven large high-income countries.

But like the draft version, the final department report insisted that a federal law, known as the Bayh-Dole Act, did not intend march-in rights to be used as a “price control,” and cited industry concerns over the durability of licensing rights. Moreover, NIST also maintained that the law is not clear about permitting the use of march-in rights.

“According to stakeholders, the circumstances under which the government may exercise march-in rights are not well-defined,” the report stated. “Market uncertainty is created by the lack of a clear definition of the use of march-in rights that is consistent with statute, rather than as a regulatory mechanism for the federal government to control the market price of goods and services.”

Besides complaining about price controls, drug makers are reluctant to commit to pricing terms while projects are in the early stages of development, which prompted the NIH back in 1995 to remove “reasonable pricing” clauses from cooperative R&D agreements. At the time, former NIH director Dr. Harold Varmus described the clauses as a “restraint” on new product development.

Such concerns have prompted the NIH to reject recent requests to pursue march-in rights for various medicines. In one notable example, AIDS activists last year asked the agency to use this mechanism as a way to lower the cost of the Truvada, or PrEP, HIV prevention pill, although nothing came of their effort. And KEI, along with other groups, has tried to convince the NIH to use march-in rights for a cancer drug.

“The findings point to the initial intent of the march-in rights as something to be used in the event of very special emergency sessions where technology is not being developed and advanced in the public marketplace for use by consumers,” said Copan. “Government march-in rights were never intended to be used as a price control mechanism.”

“There are other vehicles to address price controls, fair pricing, and drug availability widely, including those who have an inability to pay for those treatments,” said Copan. “It’s important to keep those separate issues. If they become inflated, it creates uncertainty for investors. March-in provisions are a safety valve where there is a national need and a licensee has not been diligent and shelved a potential valuable technology.”

But one academic argued that the findings in the report amounts to a missed opportunity.

“The proposals in the Green Paper would be accomplished by regulation rather than legislation, tying the government’s hands without Congressional action,” Brook Baker, a professor at Northeastern University School of Law and a senior policy analyst for the Health GAP advocacy group, wrote us. “These proposed march-in and government use restrictions would unilaterally disarm the federal government from its most powerful deterrents to continued and escalating monopoly pricing.”

And KEI's Love added this: "NIST is promoting an unsound theory that "available to the public on reasonable terms" means available at "any" price, regardless of how high, how unaffordable or how much higher than in any other country on earth," he wrote us.

"NIST also proposes to limit the public's royalty-free license (rights) in federally funded inventions so the right can never be used for anything other than the government's own consumption, and never as leverage to obtain fair prices on inventions the public financed.

**"In the past, the federal government march-in rights were used as leverage to block injunctions, force licensing, and even roll back price increases for the federal HIV program, although this history has been rewritten by NIST to justify new policies and regulations."**

--

Joseph P. Allen  
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---

**From:** Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]  
**Sent:** 7/9/2019 8:58:32 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: NIH's Response to KEI's Comments Regarding Exclusive License in STAT3 Inhibitor, GLG-302  
**Attachments:** b5

b5

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
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301-402-2528(Fax)

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**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Tuesday, July 09, 2019 4:35 PM  
**To:** Berkley, Dale (NIH/OD) [E] <berkeleyd@od.nih.gov>  
**Subject:** FW: NIH's Response to KEI's Comments Regarding Exclusive License in STAT3 Inhibitor, GLG-302

NCI told KEI that it would give serious consideration to all comments.

KEI asks:

1. Does the document attached to your June 19, 2019 email constitute NIH's final decision regarding KEI's comments on the GLG-302 Stat 3 Inhibitor?; and
2. What are NIH's current appeal procedures and where they are disclosed to the public?

b5

**From:** Ahsan, Sidra (NIH/NCI) [E] <sidra.ahsan@nih.gov>  
**Sent:** Tuesday, July 9, 2019 4:30 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** FW: NIH's Response to KEI's Comments Regarding Exclusive License in STAT3 Inhibitor, GLG-302

Hi Mark

Please see email below. Richard asked me to consult with you regarding this.

b5

b5

Best  
Sidra

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Tuesday, July 9, 2019 3:05 PM  
**To:** Ahsan, Sidra (NIH/NCI) [E] <sidra.ahsan@nih.gov>  
**Cc:** James Love <james.love@keionline.org>  
**Subject:** NIH's Response to KEI's Comments Regarding Exclusive License in STAT3 Inhibitor, GLG-302

Dear Dr. Ahsan:

REL0000023921

On June 19, 2019, you emailed James Love, Director of Knowledge Ecology International (KEI), in response to our comments regarding the "Prospective Grant of an Exclusive Patent License: The Development and Use of a Therapeutic STAT3 Inhibitor, GLG-302, in All Proliferative Diseases, Where STAT3 Is Present, to GLG Pharma LLC located in Jupiter, Florida, USA."

A document attached to the email stated, in pertinent part: "We consider all comments prior to negotiating the proposed license. We will give your comments and suggestions serious consideration."

At 2:27 p.m. the same day, Mr. Love replied to your email and asked whether KEI will hear from NIH if it decides to proceed on the proposed license or accept or reject our suggestions. He also asked about the procedures for appealing under 37 C.F.R. § 404.11. You did not respond, and the link to the appeals procedure on NIH's website continues to be broken.

As soon as practicable, please clarify the following:

1. Does the document attached to your June 19, 2019 email constitute NIH's final decision regarding KEI's comments on the GLG-302 Stat 3 Inhibitor?; and
2. What are NIH's current appeal procedures and where they are disclosed to the public?

Thank you in advance for your consideration.

Sincerely,

--

Kathryn Ardizzone, Esq.  
Knowledge Economy International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670

**b5**

**b5**



**b5**

---

**From:** jamespackardlove@gmail.com [jamespackardlove@gmail.com]  
**on behalf of** Jamie Love [james.love@keionline.org]  
**Sent:** 1/11/2017 7:08:28 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]  
**CC:** Claire Cassedy [claire.cassedy@keionline.org]  
**Subject:** For Mark

Mark, is there someone at the NIH that Claire can talk to about the policy on publishing notices about CRADAs?

We were surprised at few notices we found in the Federal Register.

Jamie

--

James Love. Knowledge Ecology International

<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,

[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

---

**From:** Lambert, Richard (NIH/NIAID) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9668E9326D084AC893665B084FDFD4FE-LAMBERTR]  
**Sent:** 12/1/2017 1:09:43 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW: [Ip-health] BioCentury: NIH WON'T USE MARCH-IN TO LOWER PRICES

FYI

Richard A. Lambert  
Contractor  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health  
U.S. Department of Health and Human Services  
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Bethesda, MD 20892-9804  
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-----Original Message-----

**From:** James Love [mailto:james.love@keionline.org]  
**Sent:** Thursday, November 30, 2017 5:56 PM  
**To:** Ip-health <ip-health@lists.keionline.org>  
**Subject:** [Ip-health] BioCentury: NIH WON'T USE MARCH-IN TO LOWER PRICES

BioCentury has this report on a hearing today, where Dr. Francis Collins to Representative Jan Schakowsky that the NIH did not the authority under the Bayh-Dole Act to deal with excessive prices, only non available of products. Of course, that's not true. This is Steve Usdin's report, followed by a short commentary on the Bayh-Dole Act provisions. Jamie

The BioCentury story:

<https://www.biocentury.com/bc-extra/politics-policy/2017-11-30/nih-won%E2%80%99t-use-march-lower-prices>

NOV 30, 2017  
NIH WON'T USE MARCH-IN TO LOWER PRICES  
BY STEVE USDIN

NIH Director Francis Collins said at congressional hearing on Thursday that the agency will not use "march-in" rights over medical products patented by the institutes or its grantees as a tool to lower drug prices.

Collins was responding to a question from Rep. Jan Schakowsky (D-Ill.) about NIH's legal authority under the Bayh-Dole Act to terminate an exclusive license and allow competitors to manufacture a drug. The march-in provisions are intended "to cover a circumstance when a drug isn't available to the public at any cost," not to intervene when a drug price is unreasonable, Collins said. He added that NIH's "legal experts" have advised him that NIH can't terminate a license based on a drug's price.

Jamie Love, director of Knowledge Ecology International (KEI), a non-profit organization that has vigorously lobbied NIH to use march-in rights to lower drug prices, accused Collins of misstating the law. In a comment posted on Twitter, Love noted that the Bayh-Dole Act requires inventions be "available to the public on reasonable terms." He also pointed to language in the law that instructing the government to "protect the public against nonuse or unreasonable use of inventions."

In June NIH declined a request from KEI for it to exercise march-in rights to allow generic competition for prostate cancer treatment Xtandi enzalutamide (see BioCentury Extra, June 20).

End.

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REL0000023926

A few notes on the law:

35 USC 200 describes the policy and objectives of the Bayh-Dole Act, and that includes:

"to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions"

Note that this includes both "nonuse" and "unreasonable use."

Patent holders have an obligation to bring an invention to "practical application." And while that might sound like just getting it in a store for sale, which is what Collins asserted today, the term is defined in the statute, 35 USC 201(f), to mean "available to the public on reasonable terms." It is hard to parse that without seeing a requirement that the price be reasonable.

Aside from this, the government has a royalty free right in all patents it funds, and that certainly gives it all the leverage it needs to deal with prices. See: 35 USC 202(c)4 and 35 USC 209(d).

The termination provision for NIH owned licenses is 35 USC 209(d)(3)(A), which is read in light of definition of "practical application" in 201(f), the requirement to make inventions "available to the public on reasonable terms."

--

James Love. Knowledge Ecology International <http://www.keionline.org/donate.html>  
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+41.76.413.6584, [twitter.com/jamie\\_love](https://twitter.com/jamie_love)

---

Ip-health mailing list  
[Ip-health@lists.keionline.org](mailto:Ip-health@lists.keionline.org)  
[http://lists.keionline.org/mailman/listinfo/ip-health\\_lists.keionline.org](http://lists.keionline.org/mailman/listinfo/ip-health_lists.keionline.org)

---

**From:** Bradley, David (NIH/NIDCR) [E] [/O=NIH/OU=NIHEXCHANGE/CN=NIDCR/CN=BRADLEYDA]  
**Sent:** 5/23/2016 2:13:06 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]; Rodriguez, Richard (NIH/NCI) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=RODRIGUR]  
**Subject:** Legal Basis for Commencing Negotiations  
**Attachments:** NIHAquaporinKEI160416.pdf

Dear Mark and Richard,

NIDCR received written comments from KEI regarding our Federal Register, Prospective Grant of Exclusive License Notice published on April 22, 2016 (see <https://www.federalregister.gov/articles/2016/04/29/2016-09978/prospective-grant-of-exclusive-license-aav-mediated-aquaporin-gene-transfer-to-treat-sjgrens>).

The comments (attached) were very similar to those received by other NIH institutes;

b5

b5

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However, NIDCR is required to consider these comments before granting an exclusive license. As is customary, we will respond to KEI in writing.

NIDCR's obligation is to promote the utilization of inventions arising from federally supported research or development.

b5

Thank you both very much for your continued assistance and advice in licensing matters.

Regards,  
David



NIHAquaporinKE...

David William Bradley, Ph.D.  
Director, Office of Technology Transfer and Innovation Access (OTTIA)  
National Institute of Dental and Craniofacial Research (NIDCR)  
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cell b5

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REL0000023928





May 16th, 2016

Sally Hu, Ph.D., M.B.A.,  
Senior Licensing and Patenting Manager,  
Office of Technology Transfer and Innovation Access,  
National Institute of Dental and Craniofacial Research,  
National Institutes of Health,  
BLDG 1 DEM, RM667, 6701 Democracy Blvd.,  
Bethesda, MD 20817  
Telephone: (301) 594-2616  
Facsimile: (301) 496-1005  
Email: sally.hu@nih.gov.

**Re: Prospective Grant of Exclusive License: AAV-Mediated Aquaporin Gene Transfer To Treat Sjögren's Syndrome**

Dear Dr. Hu,

Knowledge Ecology International (KEI) is responding to the Notice published in the Federal Register on April 29, 2016, entitled "Prospective Grant of Exclusive License: AAV-Mediated Aquaporin Gene Transfer To Treat Sjögren's Syndrome" (81 FR 25683), available at: <https://federalregister.gov/a/2016-09978>.

The National Institutes of Health is considering the grant of a worldwide exclusive license for United States government-owned patents relating to "AAV-mediated aquaporin gene transfer to treat Sjögren's syndrome" to MeiraGTx, comprising the following intellectual property:

- U.S. Provisional Patent Application No. 61/695,753;
- PCT Application No. PCT/US2013/057632;
- Australia Patent Application No. 2013308470;
- Canada Patent Application No. 2882763;
- European Patent Application No. 13773443.0; and
- U.S. Patent Application No. 14/423,774.

According to the Federal Register notice, the field of use may include "adeno-associated virus (AAV) vector mediated gene delivery of human aquaporin-1 (hAQP1) in Sjögren's syndrome patients with associated xerostomia and/or xerophthalmia."

KEI opposes the grant of exclusive license in this case unless:

1. The NIH conducts sufficient analysis and limits the terms and scope of the license as required under 37 CFR 404.7 (a)(1)(iiii);
2. The license contains sufficient safeguards regarding affordability and reasonable pricing of the products developed under the patent licenses;
3. The license places restrictions on charging US residents higher prices than the median prices charged in countries with the seven largest GDP and per capita incomes of 50 percent or more than the United States per capita income;
4. The license requires products are affordable in developing countries, and explicitly allows the NIH to grant licenses to the patents to the Medicines Patent Pool (MPP) for use in developing countries; and
5. The license requires transparent reporting on drug development costs, royalties and revenues.

### **About the commenters**

Knowledge Ecology International (KEI) is a nongovernmental organization based in Washington, DC, with an office in Geneva, Switzerland, that advocates for access to affordable medicines, with a focus on human rights and social justice. For more information, see: <http://keionline.org>.

### **Why the may AAV mediated gene transfer of aquaporin-1 be important**

Sjögren's syndrome is a chronic autoimmune disease where endocrine glands, such as those secreting tears or saliva, are destroyed primarily by the individual's T lymphocytes. This disease affects one to four million Americans and 35 million people worldwide.<sup>1,2</sup> Salivary gland damage can also affect those undergoing radiation therapy — such as cancer patients — and those individuals can benefit from treatments developed for Sjögren's syndrome.

People living with Sjögren's syndrome typically present with dry eyes and mouth, but the syndrome can also affect other mucous membranes. Unfortunately, as there is no treatment for this syndrome, the current standard therapy is restricted to symptom management.

In 1997, the NIH found that gene transfer of Aquaporin-1 increased salivary secretion in mice with irradiated damaged glands.<sup>3</sup> Aquaporin-1 gene therapy was first used in patients who suffered from salivary hypofunction caused by radiation therapy.<sup>4</sup>

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<sup>1</sup> <http://www.ninds.nih.gov/disorders/sjogrens/sjogrens.htm>

<sup>2</sup> Z. Lai *et al.* Aquaporin gene therapy corrects Sjögren's syndrome phenotype in mice. *Proc Natl Acad Sci U S A.* 2016 May 2.

<sup>3</sup> C. Delporte *et al.* Increased fluid secretion after adenoviral-mediated transfer of the aquaporin-1 cDNA to irradiated rat salivary glands. *Proc Natl Acad Sci U S A.* 1997 Apr 1;94(7):3268-73.

<sup>4</sup> B. Baum. Development of a gene transfer-based treatment for radiation-induced salivary hypofunction. *Oral Oncol.* 2010 Jan;46(1):4-8



Most methods of gene delivery to salivary glands, including liposomal transfection and other viral transduction methods, are highly inefficient and can induce local inflammation.<sup>5</sup> In contrast, AAV transduction have been found to be superior to other methods and sustain gene expression while avoiding an inflammatory response.

Success of an AAV based gene therapy would mean treatment for a condition that is currently incurable.

### **The role of the NIH in the development of the AAV mediated gene transfer of aquaporin-1**

Dr. John Chiorini, a senior investigator at the National Institute of Dental and Crainiofacial Research (NIDCR) and inventor of the technology for the license currently under consideration, has worked on Adeno-Associated Virus vectors since 1994. Since 2007 his lab has received NIH funding totaling \$17,686,279 for a research project entitled “Adeno-Associated Virus and utilization for Gene Transfer” (NIH Project # 1ZIADE000695, 8-16). This project produced approximately 92 peer reviewed publications, and 5 patents (see table below).

Patent Number	Patent Title
8927269	Avian adeno associated virus and uses thereof
8137960	Bovine adeno-associated viral (BAAV) vector and uses thereof
8685722	Bovine adeno-associated viral (BAAV) vector and uses thereof
8808684	Epidermal growth factor receptor (EGFR) and methods of use in adenoviral-associated virus type 6 (AAV6) transduction
8283151	Isolation, cloning and characterization of new adeno-associated virus (AAV) serotypes

Currently, Dr. Chiorini is the senior investigator in an upcoming phase 1/2 clinical trial entitled “Safety of a Single Administration of AAV2hAQP1, an Adeno-Associated Viral Vector Encoding Human Aquaporin-1 to One Parotid Salivary Gland in People With Irradiation-Induced Parotid Salivary Hypofunction” (NCT02446249), sponsored by the NIDCR. A primary objective is to assess the safety of AAV2hAQP1 gene therapy in humans.

Dr. Ilias G Alevizos, also an NIDCR investigator, conducted an earlier phase 1/2 clinical trial to study the “Effect of AdhAQP1 on Salivary Flow in Patients Treated With Radiation for

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<sup>5</sup> R. Zufferey, P. Aebischer. Salivary glands and gene therapy: the mouth waters. Gene Ther. 2004 Oct;11(19):1425-6.

Head and Neck Cancer” (NCT00372320). This was the first time the aquaporin-1 gene was delivered to humans using adenoviral vectors.

Both clinical trials investigate the use of AAV vectors to deliver the hAQP1 gene in Humans.

Gene therapy is still highly experimental, so determining the right delivery mechanisms is key in moving this technology forward. Of the many gene therapy strategies funded by the NIH, it has brought the application of AAV in salivary gland dysfunction to Phase 1 clinical trials. Considering the investment and the risk taken on by the NIH to develop this technology, it is important to include reasonable pricing assurances in any licenses that may be granted on this technology.

### **Why patent license terms are important**

We are concerned that the NIH exclusive licensing of patent rights of AAV mediated gene transfer of aquaporin-1 to MeiraGTx will result in:

1. MeiraGTx would require U.S. residents to pay more than other countries for a AAV mediated gene transfer of aquaporin-1 developed at public expense (see <http://keionline.org/xtandi> for a petition to the NIH relating to a prostate cancer drug invented at UCLA on federal grants and priced far higher in the United States than in any other country);
2. Delays in the entry of competitive suppliers for the manufacturing and distribution of the MeiraGTx that will increase affordability and reduce supply shortages; and
3. Barriers to innovation, including enhancements that make the therapy more effective in low resource settings.

### **Federal regulations on the use of exclusive licenses**

As noted in the Federal Register notice, the licenses are expected to comply with the public safeguards found in 35 U.S.C. § 209 and 37 CFR part 404.

Specifically, we are concerned about the obligations in 35 U.S.C. § 209(a)

#### ***§209. Licensing federally owned inventions***

(a) Authority.—A Federal agency may grant an exclusive or partially exclusive license on a federally owned invention under section 207(a)(2) only if—

(1) granting the license is a reasonable and necessary incentive to—

(A) call forth the investment capital and expenditures needed to bring the invention to practical application; or

(B) otherwise promote the invention's utilization by the public;

(2) the Federal agency finds that the public will be served by the granting of the license, as indicated by the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public, and that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public;

(3) the applicant makes a commitment to achieve practical application of the invention within a reasonable time, which time may be extended by the agency upon the applicant's request and the applicant's demonstration that the refusal of such extension would be unreasonable;

(4) granting the license will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws; and

(5) in the case of an invention covered by a foreign patent application or patent, the interests of the Federal Government or United States industry in foreign commerce will be enhanced.

We also note that the term "practical application" is defined by 35 U.S.C. 201(f) as follows:

(f) The term "practical application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms. [emphasis added]

Under 37 CFR 404.7(a), the NIH is required to make determinations regarding the necessity of the grant of an exclusive license:

(1) Exclusive, co-exclusive or partially exclusive domestic licenses may be granted on Government owned inventions, only if

...

(ii) After expiration of the period in § 404.7(a)(1)(i) and consideration of any written objections received during the period, the Federal agency has determined that;

(A) The public will be served by the granting of the license, in view of the applicant's intentions, plans and ability to

bring the invention to the point of practical application or otherwise promote the invention's utilization by the public.

(B) Exclusive, co-exclusive or partially exclusive licensing is a reasonable and necessary incentive to call forth the investment capital and expenditures needed to bring the invention to practical application or otherwise promote the invention's utilization by the public; and

(C) The proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public[.]

We ask the NIH to provide additional assurances that the products developed under this license be made available to the public at prices that are reasonable and affordable. Among other things, this can include a provision in the license that states:

The NIH will normally expect the licensee to make products available to the public in the United States at prices no higher than the median price charged in the seven countries with the largest GDP, that have per capita incomes of at least half that of the United States.

If the geographic area includes worldwide rights, the products should be made available at affordable prices in developing countries.

However, as far as we know, the NIH has not demonstrated why granting an exclusive license to the company is necessary. We request that the NIH or NIDCR provide public evidence that the NIH has determined an exclusive license is necessary for the development of the patented inventions, and there exists a written analysis which establishes that this evaluation has been done. Calling for public comment on the license, and then providing almost none of the relevant information, makes the public comment process ineffective, as regards the public's role in objecting to licenses that undermine their rights to obtain access to the benefits of the inventions on favorable terms, or in addressing other public interest issues.

The NIH should also have the option of providing a non-exclusive license to the Medicines Patent Pool (MPP) to permit competitive supply by generic drug manufacturers, for use in developing countries. Here we note that GSK has recently announced it has begun negotiations with the MPP to license the patents for its oncology products. Certainly the NIH can be at least as sensitive to the health needs of patients living in developing countries as is the big pharma company GSK.

Since the statute requires that the "scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application" we



request a copy of any analysis, if any, that was done to consider how many years of exclusive rights were necessary to bring the invention to practical application. We also propose the following terms for the contract:

The exclusive rights will extend to five years from the first sale of a product receiving approval by the U.S. FDA, or until the license holder recovers at least \$1 billion in global sales from the product, whichever is shorter, and thereafter, the license will become non-exclusive. After the first five years of exclusivity, the NIH can extend the exclusivity by another 3 years, upon a showing that such extension is reasonable in light on the risk adjusted R&D costs to bring the product market, and the net revenues from sales.

KEI notes that the 5 year period, with possible extensions, follows NIH practice, prior to 1984, and other NIH licenses have had terms shorter than the life of patent. For example, in October 2001, the NIH exercised an option to make the licenses for the AIDS drug DDI non-exclusive, ten years after the initial FDA registration (see: Videx® Expanding Possibilities: A Case Study, NIH, National Institutes of Health Office of Technology Transfer, September 2003) in order to expand access to the drug, and to obtain lower cost supplies for federal programs.

The NIH could consider different time periods for exclusivity, but if the answer is always life of patent, no matter what the facts are, then the NIH is no longer meeting the requirements of 35 U.S.C. § 209 to ensure that the “scope of exclusivity is not greater than reasonably necessary.”

## **Transparency**

KEI is also asking for more transparency regarding the costs of developing new products, and the pricing, sales and royalty payments on products.

We object to any license that is not made public. Moreover, all reports specified in the license, including those described in the license appendices, should be public. If the NIH insists on transparency (as was common practice and acceptable in earlier years), [Company] would agree. The company is getting the license before making any significant investments, and the NIH’s invention may be worth several billion dollars.

We ask the NIH to create a requirement for annual reports on R&D outlays, including an obligation that the company reports the following for each clinical trial that tests products covered by the patents:

1. ClinicalTrials.Gov identifier
2. Phase
3. Conditions
4. Interventions
5. Title Acronym/Titles

6. Outcome Measures
7. Sponsor/Collaborators
8. Other Study IDs
9. Expenditure (for that year)

With regard to sales prices, we request an annual report that provide data on the following variables:

1. Units of sales, by country
2. Revenue for sales, by country

With regard to government subsidies for research, we request a report that provides data for the following, by year:

1. Grants and research contracts from government agencies, with data on the funding agency, the identifier of the grant or contract, and the amount of the grant or contract;
2. Tax credits associated with R&D for the product, including the U.S. orphan drug tax credit, broken out by the type of credit and the expenditure the credit was associated with (such as a specific trial); and
3. Other government R&D subsidies.

We hope the NIH will seriously consider these comments, and use its authority to advance affordable access to medical technologies that will benefit the overall health of the American public and society at large.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Diane Singhroy". The signature is stylized with a large, looped "D" and a cursive "Singhroy".

Diane Singhroy  
Scientific and Technical Advisor  
Knowledge Ecology International  
1621 Connecticut Avenue, Suite 500  
Washington, DC 20009  
+1 (202) 332-2670  
[diane.singhroy@keionline.org](mailto:diane.singhroy@keionline.org)

---

**From:** Rodriguez, Richard (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8092CB5394E04733AC0D4D84D25F65E5-RODRIGR]  
**Sent:** 9/21/2017 7:02:11 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: KEI Response

Mark,

I was looking at this again and think a quick call would help if you have a moment? If so, what number may I reach you at?

Thanks,

Richard

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Thursday, September 21, 2017 2:43 PM  
**To:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
**Subject:** RE: KEI Response

**b5**

**From:** Rodriguez, Richard (NIH/NCI) [E]  
**Sent:** Thursday, September 21, 2017 1:43 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** KEI Response

Hi Mark,

I'm following up on this request for input on a NCI response to a KEI comment. Karen Maurey mentioned this topic to me in a meeting this morning, and that you had commented **b5** **b5** (TDC-Short meeting I think). Also, this relates to what I wrote you about this morning, and so I just want to make sure we are all on the same page.

Thanks,

Richard

---

**RICHARD U. RODRIGUEZ, M.B.A.**  
Associate Director  
Patent Agent

Technology Transfer Center  
National Cancer Institute  
National Institutes of Health  
9609 Medical Center Drive, Rm 1E530

REL0000023930

Bethesda, MD 20892-9702 (for business mail)  
Rockville, MD 20850-9702 (for courier service/visitors)  
Phone (Main Office): 240-276-5530  
Direct phone: 240-276-6661  
Fax 240-276-5504  
[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)

<https://techtransfer.cancer.gov>

"Start by doing what's necessary; then do what's possible; and suddenly you are doing the impossible" - Francis of Assisi

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**From:** Hammersla, Ann (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=87FB28AA23744C0B855EF0683AC2E8B4-HAMMERSLAA]  
**Sent:** 6/14/2018 3:02:55 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]; Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodrigr]; Lambertson, David (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c95b34f709746a8a2553ce54e74ace2-lambertsond]  
**Subject:** RE: [REDACTED] b5

[REDACTED] b5

[REDACTED] b5

Ann

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Thursday, June 14, 2018 10:16 AM  
**To:** Fine, Amanda (NIH/OD) [E] <amanda.fine@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Wojtowicz, Emma (NIH/OD) [E] <emma.wojtowicz@nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>; Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>  
**Subject:** Fwd: [REDACTED] b5

[REDACTED] b5

Mark

Sent from my iPhone

Begin forwarded message:

**From:** "Berkley, Dale (NIH/OD) [E]" <berkeleyd@od.nih.gov>  
**Date:** June 14, 2018 at 9:38:45 AM EDT  
**To:** "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>  
**Subject:** [REDACTED] b5

[REDACTED] b5

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHID, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
301 496 6043  
301-402-2528(Fax)

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REL0000023932

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**From:** Greene, Jaime (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E06E39F0BCD34511A92DF20C5DC8722A-GREENEJAIME]  
**Sent:** 4/22/2019 9:01:04 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW: Morphix license  
**Attachments:** 84 FR 1764 ResponseToComments.pdf

Mark,  
Attached is the letter I emailed to KEI today. Below is KEI's response.

Do you want to respond to the email below?

Thanks,  
Jaime

Jaime Meredith Greene, M.S.  
Senior Technology Transfer Manager  
NCI Technology Transfer Center

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**From:** James Love <james.love@keionline.org>  
**Sent:** Monday, April 22, 2019 4:57 PM  
**To:** Greene, Jaime (NIH/NCI) [E] <greenejaime@mail.nih.gov>  
**Cc:** Luis Gil Abinader <luis.gil.abinader@keionline.org>  
**Subject:** Re: Morphix license

Thank you.

Did the NIH request the advice of the Attorney General, as is required by

40 U.S. Code § 559 – Advice of Attorney General with respect to antitrust law.

Jamie

On Mon, Apr 22, 2019 at 4:14 PM Greene, Jaime (NIH/NCI) [E] <greenejaime@mail.nih.gov> wrote:

Dear James Love,

Attached please find our response to your comments on 84 FR 1764.

Best,

Jaime

Jaime Meredith Greene, M.S.  
Senior Technology Transfer Manager

NCI Technology Transfer Center

**Note:** This email may contain confidential information. If you are not the intended recipient, any disclosure, copying or use of this email or the information enclosed therein is strictly prohibited, and you should notify the sender for return of any attached documents

REL0000023933

--

James Love. Knowledge Ecology International

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<http://www.keionline.org>

[twitter.com/jamie\\_love](https://twitter.com/jamie_love)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health/ NCI  
9609 Medical Center Drive, Suite 530  
Rockville, MD 20852  
Office (240) 276-5530  
Facsimile (240) 276-5504

*via email only*

April 22, 2019

James Love  
Knowledge Ecology International (KEI)  
1621 Connecticut Avenue, Suite 500,  
Washington DC 20009

RE: Prospective Grant of an Exclusive Patent License: Use of the CD47 Phosphorodiamidate Morpholino Oligomers for the Treatment, Prevention, and Diagnosis of Solid Tumors (84 FR 1764)

Dear Mr. Love,

Thank you for providing us with your comments in response to the Federal Register Notice of the proposed license to Morphiex Biotherapeutics (Morphiex) by the National Cancer Institute (NCI). We have reviewed and considered all of your comments and the specific recommendations you provided regarding terms to be included in the license related to the pricing of products, the term of exclusivity, the exclusivity and access in developing countries, and the transparency of the licensee's development through annual reporting.

As we previously stated in response to your comments on 83 FR 30448, with respect to your comments regarding the pricing of products in the US and developing countries, the NIH has not included terms related to pricing in its licenses for many years. The reasons for this are well established and are publicly available. Also, with respect to your comments regarding transparency of information regarding clinical trial outlays and research and development costs by the licensee, these are business confidential information that, under the licensing statute cannot be disclosed.

Therefore, NCI has determined that your objection did not raise an issue that would preclude the grant of the proposed exclusive license, and the NCI intends to proceed with the negotiation of the proposed exclusive license.

Sincerely,  
Jaime M. Greene, M.S.  
Senior Technology Transfer Manager  
NCI Technology Transfer Center

REL0000023933.0001

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**From:** Hammersla, Ann (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=87FB28AA23744C0B855EF0683AC2E8B4-HAMMERSLAA]  
**Sent:** 7/26/2019 10:50:22 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: Pharmaset 7,964,580

No. b5 Ann

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Thursday, July 25, 2019 4:48 PM  
**To:** Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>  
**Subject:** Pharmaset 7,964,580

Ann:

b5

<https://www.keionline.org/27205>

<https://www.keionline.org/wp-content/uploads/2018/03/HHS-Azar-KEI-Patent-7964580-SOF-14March2018.pdf>

Mark

Mark L. Rohrbaugh, Ph.D., J.D.  
Special Advisor for Technology Transfer  
Office of Science Policy  
National Institutes of Health

Mark:: A start:

**b5**

I think that we can also use some language b5

**b5**

**b5**

**b5**

**From:** Hammersla, Ann (NIH/OD) [E]  
**Sent:** Thursday, May 04, 2017 9:57 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[RohrBauM@OD.NIH.GOV](mailto:RohrBauM@OD.NIH.GOV)>  
**Subject:** RE: royalties

Good Morning: I am just pulling up the OGC comments.

**b5**

**b5**

**b5**

If you would like to draft I am on-line for most of the morning. Ann

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Thursday, May 04, 2017 9:47 AM  
**To:** Hammersla, Ann (NIH/OD) [E] <[hammerslaa@mail.nih.gov](mailto:hammerslaa@mail.nih.gov)>  
**Subject:** Re: royalties

The revised KEI letter is due today. If I take a stab at it, are you able to look it over today?

Sent from my iPhone

On May 4, 2017, at 9:32 AM, Hammersla, Ann (NIH/OD) [E] <[hammerslaa@mail.nih.gov](mailto:hammerslaa@mail.nih.gov)> wrote:

Good Morning: Thanks Mark for adding the additional information. I am at the NIH Regional meeting and yesterday was a workshop on IP.

Ann

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Wednesday, May 03, 2017 4:36 PM  
**To:** Tabak, Lawrence (NIH/OD) [E] <[Lawrence.Tabak@nih.gov](mailto:Lawrence.Tabak@nih.gov)>  
**Cc:** Wolinetz, Carrie (NIH/OD) [E] <[carrie.wolinetz@nih.gov](mailto:carrie.wolinetz@nih.gov)>; Hammersla, Ann (NIH/OD) [E] <[hammerslaa@mail.nih.gov](mailto:hammerslaa@mail.nih.gov)>  
**Subject:** RE: royalties

REL0000023935



I believe Ann is on official travel. Here is my revision.

**From:** Tabak, Lawrence (NIH/OD) [E]

**Sent:** Wednesday, May 03, 2017 2:33 PM

**To:** Rohrbaugh, Mark (NIH/OD) [E] <[RohrBauM@OD.NIH.GOV](mailto:RohrBauM@OD.NIH.GOV)>; Hammersla, Ann (NIH/OD) [E] <[hammerslaa@mail.nih.gov](mailto:hammerslaa@mail.nih.gov)>

**Cc:** Wolinetz, Carrie (NIH/OD) [E] <[carrie.wolinetz@nih.gov](mailto:carrie.wolinetz@nih.gov)>

**Subject:** royalties

**Importance:** High

Mark, Ann-

Please see FC comments on your proposal. Could you please address questions/comments and return to me asap?

Thanks

Larry

---

**From:** Lambert, Richard (NIH/NIAID) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9668E9326D084AC893665B084FDFD4FE-LAMBERTR]  
**Sent:** 11/30/2017 6:41:14 PM  
**To:** Rohrbough, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW: [Ip-health] What does the Orphan Drug Tax Credit tell us about the costs of clinical trials? | Bill of Health

FYI

Richard A. Lambert  
Contractor  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health  
U.S. Department of Health and Human Services  
5601 Fishers Lane, Rm. 2G47, MSC 9804  
Bethesda, MD 20892-9804  
(Courier: Rockville, MD. 20852)  
301.496.2644 main officeline  
240.627.3706 direct line  
FAX 240.627.3117  
lambertr@niaid.nih.gov

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-----Original Message-----

From: James Love [mailto:james.love@keionline.org]  
Sent: Wednesday, November 15, 2017 11:26 AM  
To: Michael H Davis <m.davis@csuohio.edu>  
Cc: Ip-health <ip-health@lists.keionline.org>  
Subject: Re: [Ip-health] What does the Orphan Drug Tax Credit tell us about the costs of clinical trials? | Bill of Health

<http://blogs.harvard.edu/billofhealth/2017/11/15/what-does-the-orphan-drug-tax-credit-tell-us-about-drug-development-costs/>

Summary:

The number of patients enrolled in the trials used to support the registration of novel orphan product are significantly smaller than non-orphan products. One measure of this is the difference in the enrollment of trials cited in the FDA drug trials snapshots.

Since 2015, the average number of trials cited in the FDA trials snapshots for novel drugs were 439 for orphan products, and 2,736 for non-orphans. Data from the Orphan Drug Tax Credit provides insights into the costs of drug development, or more specially, the costs of the clinical trials used to support an FDA approval.

From 2010 to 2016, the average qualifying trial costs claimed for the orphan drug credit was \$86 million to \$102 million, per FDA approved orphan indication (assuming 2 to 3 year average years of lag between the credit claimed and the approval date). Companies were able to take a credit of \$43 to \$51 million, on average, for each FDA approval.

The \$86 to \$102 million in pre-credit outlays is far lower than the average of \$965 million on trial costs for a new drug approval, estimated by DiMasi and others in 2016. Some of the differences are explained by the smaller trials for orphan drugs and other differences in methodologies, although both figures include the costs of failed trials and exclude pre-clinical or cost of capital costs.

In 2013, the last year for which we have actual rather than projected data on the credit (from the IRS Statistics of Income), the total amount of the credit from all 132 corporate tax returns that claimed the credit was just over \$1 billion, nearly the same amount as the DiMasi estimate of \$965 million for a single drug. But in 2013, the FDA granted 265 orphan designations and approved 33 orphan indications, including 8 novel products which were approved for an orphan drug lead indication.

The data from the orphan drug tax credit illustrates the large gap between the known facts about the costs for R&D for orphan drug development, and the astronomically larger R&D costs claimed by DiMasi (and

REL0000023936

frequently quoted by other researchers, policy makers and journalists) as averages that should guide policy making.

These data underline the need for greater transparency of R&D costs, and more sophistication and realism by policy makers regarding the costs of research and development for drugs qualifying as orphan products.

The data from the orphan drug tax credit also provides additional perspective on the estimates of drug development costs provided by Vinay Prasad and Sham Mailankody in their 2017 JAMA paper.

On Wed, Nov 15, 2017 at 5:02 PM, Michael H Davis <m.davis@csuohio.edu> wrote:

>  
> I understand generally but maybe if there were a quick takeaway, as my students now say (basically it means they don't want to study and read, which now seems to apply to me), it should help. But now I'm going to read the whole thing.

>  
> Mickey

>  
>  
>  
>  
> Sent from my T-Mobile 4G LTE Device

>  
>  
> ----- Original message -----  
> From: James Love <james.love@keionline.org>  
> Date: 11/15/17 9:51 AM (GMT-05:00)  
> To: Ip-health <ip-health@lists.keionline.org>  
> Subject: [Ip-health] What does the Orphan Drug Tax Credit tell us  
> about  
the costs of clinical trials? | Bill of Health

>  
> This is an analysis of the data from the orphan drug tax credit, which  
> is

a  
> subsidy for 50 percent of the costs of qualifying clinical trials.  
> The nuances of how the credit is calculated are described, I compare  
> data from the FDA drug trials snaps on the size of enrollment in the  
> trials for orphan drugs to non-orphans. Perhaps of most interest will  
> be the data on the amount of credit taken, by all taxpayers, and the  
> orphan designations and approvals, and the calculations of the credit  
> per designation and per FDA approved indication.

>  
>  
http://blogs.harvard.edu/billofhealth/2017/11/15/what-does-the-orphan-drug-tax-credit-tell-us-about-drug-development-costs/

>  
-----  
> Ip-health mailing list  
> Ip-health@lists.keionline.org  
> http://lists.keionline.org/mailman/listinfo/ip-health\_lists.keionline.  
> org

--  
James Love. Knowledge Ecology International <http://www.keionline.org/donate.html>  
KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile:  
+41.76.413.6584, [twitter.com/jamie\\_love](https://twitter.com/jamie_love)

-----  
Ip-health mailing list  
Ip-health@lists.keionline.org  
[http://lists.keionline.org/mailman/listinfo/ip-health\\_lists.keionline.org](http://lists.keionline.org/mailman/listinfo/ip-health_lists.keionline.org)

---

**From:** Burklow, John (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2E57F267323B43C08BE856ACB5B964CA-BURKLOWJ]  
**Sent:** 6/29/2018 2:55:53 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Gottesman, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=918c2344931542a592d00dbe83d3d5a3-gottesmm]; Jorgenson, Lyric (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbde7d361374981a4d336b6eeb17521-jorgensonla]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Harris, Melissa (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cab5d3a8edc46519f7e8165cd2ddd34-mjharris]  
**Subject:** RE: 83 FR 30448, Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

Right. I agree with you, Mark, and I'm happy to meet with you and Dale and others on [b5] I've cc'd Missy, who will help us find a time.

Thanks,

John

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Friday, June 29, 2018 10:54 AM  
**To:** Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>  
**Cc:** Gottesman, Michael (NIH/OD) [E] <gottesmm@mail.nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>  
**Subject:** FW: 83 FR 30448, Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

John:

We could use your help with this.

[b5]

b5

Regards,  
Mark

---

**From:** Freil, Rose (NIH/NCI) [E]  
**Sent:** Friday, June 29, 2018 9:26 AM

REL0000023938

**To:** Rohrbaugh, Mark (NIH/OD) [E] <[RohrBauM@OD.NIH.GOV](mailto:RohrBauM@OD.NIH.GOV)>

**Cc:** Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>

**Subject:** FW: 83 FR 30448, Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

Hi Mark,

See email below from KEI regarding a FR Notice for intent to grant. Let me know when you have time to discuss.

Thanks!

Rose

--

Rose Santangelo Freel, Ph.D.

Technology Transfer Manager

**National Cancer Institute**

P 301-624-1257 | [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

**From:** James Love [<mailto:james.love@keionline.org>]

**Sent:** Thursday, June 28, 2018 4:04 PM

**To:** Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)>

**Cc:** Claire Cassedy <[claire.cassedy@keionline.org](mailto:claire.cassedy@keionline.org)>

**Subject:** 83 FR 30448, Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

Rose M. Freel, Ph.D.,

Licensing and Patenting Manager,

NCI Technology Transfer Center,

8490 Progress Drive, Suite 400, Frederick, MD 21701;

Email: [rose.freel@nih.gov](mailto:rose.freel@nih.gov).

Dear Dr

Freel,

Has the technology referred to in 83 FR 30448, regarding Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer, been subject to any clinical trials (1) funded by the NIH, or (2) funded by any other party?

This information is useful for KEI in preparing our comments on the license.

Jamie

--

James Love. Knowledge Ecology International

<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, [twitter.com/jamie\\_love](https://twitter.com/jamie_love)

REL0000023938

---

**From:** Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]  
**Sent:** 1/30/2019 9:42:28 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Soukas, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b1f6020157ac47948c6e34166b78e433-soukasp]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]; Frisbie, Suzanne (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c402740ceaad4d4f97a8c28f16fbb349-frisbies]; Williams, Richard (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5f89fe4d27a43abb936bb20efeca3b9-rwilliams]; Puglielli, Maryann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f53ceacaf754875a948081bac5cc66a-pugliellim]  
**Subject:** RE: KEI Response Letter

Looks good to me too, thanks Peter.

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
301-496-6043  
301-402-2528(Fax)

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**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Wednesday, January 30, 2019 4:40 PM  
**To:** Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>; Williams, Richard (NIH/NIAID) [E] <rwilliams@niaid.nih.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>  
**Subject:** RE: KEI Response Letter

Looks good Peter. I made a few small suggestions and ask a question for clarification. Thx

**From:** Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>  
**Sent:** Wednesday, January 30, 2019 3:54 PM  
**To:** Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>; Williams, Richard (NIH/NIAID) [E] <rwilliams@niaid.nih.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>  
**Subject:** Re: KEI Response Letter

Dear Dale and Mark,

We hope everything is going well with you. Thank you for the productive conversation last week.

REL0000023940

Attached please find a further draft letter for your review and/or approval.

Please contact us if you have any additional questions. Thank you once again for your help.

Peter Soukas  
Phone: 301-594-8730  
Email: [ps193c@nih.gov](mailto:ps193c@nih.gov)

---

**From:** Berkley, Dale (NIH/OD) [E]  
**Sent:** Wednesday, January 23, 2019 12:51 PM  
**To:** Mowatt, Michael (NIH/NIAID) [E]; Rohrbaugh, Mark (NIH/OD) [E]; Frisbie, Suzanne (NIH/NIAID) [E]; Soukas, Peter (NIH/NIAID) [E]; Williams, Richard (NIH/NIAID) [E]; Puglielli, Maryann (NIH/NIAID) [E]  
**Subject:** RE: KEI Response Letter

b5

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
301-496-6043  
301-402-2528(Fax)

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-----Original Message-----

From: Mowatt, Michael (NIH/NIAID) [E] <[mmowatt@niaid.nih.gov](mailto:mmowatt@niaid.nih.gov)>  
Sent: Tuesday, January 22, 2019 12:53 PM  
To: Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Frisbie, Suzanne (NIH/NIAID) [E] <[suzanne.frisbie@nih.gov](mailto:suzanne.frisbie@nih.gov)>; Soukas, Peter (NIH/NIAID) [E] <[peter.soukas@nih.gov](mailto:peter.soukas@nih.gov)>; Williams, Richard (NIH/NIAID) [E] <[rwilliams@niaid.nih.gov](mailto:rwilliams@niaid.nih.gov)>; Puglielli, Maryann (NIH/NIAID) [E] <[maryann.puglielli@nih.gov](mailto:maryann.puglielli@nih.gov)>  
Cc: Berkley, Dale (NIH/OD) [E] <[berkeleyd@od.nih.gov](mailto:berkeleyd@od.nih.gov)>; Mowatt, Michael (NIH/NIAID) [E] <[mmowatt@niaid.nih.gov](mailto:mmowatt@niaid.nih.gov)>  
Subject: RE: KEI Response Letter

Team,

I ran into Dale just now at NIH. b5

b5 We shouldn't need more than 15 or 30 minutes tomorrow.

Thanks Dale and everyone,

Mike

-----Original Message-----

From: Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
Sent: Tuesday, January 22, 2019 12:24 PM  
To: Mowatt, Michael (NIH/NIAID) [E] <[mmowatt@niaid.nih.gov](mailto:mmowatt@niaid.nih.gov)>  
Cc: Frisbie, Suzanne (NIH/NIAID) [E] <[suzanne.frisbie@nih.gov](mailto:suzanne.frisbie@nih.gov)>; Soukas, Peter (NIH/NIAID) [E]

REL0000023940

<[peter.soukas@nih.gov](mailto:peter.soukas@nih.gov)>; Williams, Richard (NIH/NIAID) [E] <[rwilliams@niaid.nih.gov](mailto:rwilliams@niaid.nih.gov)>; Puglielli, Maryann (NIH/NIAID) [E] <[maryann.puglielli@nih.gov](mailto:maryann.puglielli@nih.gov)>; Berkley, Dale (NIH/OD) [E] <[berkeleyd@od.nih.gov](mailto:berkeleyd@od.nih.gov)>  
Subject: Re: KEI Response Letter

Just saw this. Do you have time now?

Sent from my iPhone

> On Jan 22, 2019, at 11:59 AM, Mowatt, Michael (NIH/NIAID) [E] <[mmowatt@niaid.nih.gov](mailto:mmowatt@niaid.nih.gov)> wrote:

>

> 1-888-370-7168

> Leader - 9665858

> Participant - 1625866

>

>

> Thanks, Mary.

>

> This one is a priority, so please squeeze it in this week. Tomorrow afternoon?

>

>

>

>

>

> Dear Mary,

>

> We are just following up, we hope everything is going well with you.

>

> Does Mike have any time this week to discuss these issues with Mark Rohrbaugh and Dale Berkley?

>

> We look forward to a meeting invitation soon.

>

> Thank you.

>

> Peter

> <[meeting.ics](#)>



---

**From:** Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]  
**Sent:** 6/14/2018 2:28:52 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: [REDACTED] **b5**

Ok thanks

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
301-496-6043  
301-402-2528(Fax)

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**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Thursday, June 14, 2018 10:22 AM  
**To:** Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>  
**Subject:** Fwd: [REDACTED] **b5**

Meant to cc you. I am not in the office. I think it was addressed briefly in a response to KEI.

Sent from my iPhone

Begin forwarded message:

**From:** "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>  
**Date:** June 14, 2018 at 10:15:30 AM EDT  
**To:** "Fine, Amanda (NIH/OD) [E]" <amanda.fine@nih.gov>, "Myles, Renate (NIH/OD) [E]" <mylesr@mail.nih.gov>, "Wojtowicz, Emma (NIH/OD) [E]" <emma.wojtowicz@nih.gov>, "Rodriguez, Richard (NIH/NCI) [E]" <richard.rodriguez@nih.gov>, "Lambertson, David (NIH/NCI) [E]" <david.lambertson@nih.gov>, "Hammersla, Ann (NIH/OD) [E]" <hammerslaa@mail.nih.gov>  
**Subject:** Fwd: [REDACTED] **b5**

[REDACTED] **b5**

Mark

Sent from my iPhone

Begin forwarded message:

**From:** "Berkley, Dale (NIH/OD) [E]" <berkleyd@od.nih.gov>  
**Date:** June 14, 2018 at 9:38:45 AM EDT  
**To:** "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>  
**Subject:** [REDACTED] **b5**

[REDACTED] **b5**

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
301-496-6043  
301-402-2528(Fax)

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---

**From:** Mowatt, Michael (NIH/NIAID) [E] [/O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=MMOWATT]  
**Sent:** 6/6/2017 1:20:55 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]; Lambert, Richard (NIH/NIAID) [C] [/O=NIH/OU=NIHEXCHANGE/cn=NIAID/cn=LAMBERTR]; Berkley, Dale (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=BERKLEYD]  
**Subject:** RE: [Ip-health] KEI asks the Department of Health and Human Services to adopt a policy on licensing CRISPR patents

I believe KEI is going broader than NIH intramural.

b5

-----Original Message-----

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Tuesday, June 06, 2017 9:11 AM  
**To:** Lambert, Richard (NIH/NIAID) [C] <lambertr@niaid.nih.gov>; Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>; Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>  
**Subject:** RE: [Ip-health] KEI asks the Department of Health and Human Services to adopt a policy on licensing CRISPR patents

b5

-----Original Message-----

**From:** Lambert, Richard (NIH/NIAID) [C]  
**Sent:** Tuesday, June 06, 2017 7:52 AM  
**To:** Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>  
**Subject:** FW: [Ip-health] KEI asks the Department of Health and Human Services to adopt a policy on licensing CRISPR patents

FYI

Richard A. Lambert  
Contractor  
National Institute of Allergy and Infectious Diseases National Institutes of Health U.S. Department of Health and Human Services  
5601 Fishers Lane, Rm. 2G47, MSC 9804  
Bethesda, MD 20892-9804  
(Courier: Rockville, MD. 20852)  
301.496.2644 main officeline  
240.627.3706 direct line  
FAX 240.627.3117  
lambertr@niaid.nih.gov

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-----Original Message-----

**From:** Jamie Love [mailto:james.love@keionline.org]  
**Sent:** Tuesday, June 06, 2017 7:43 AM  
**To:** Ip-health <ip-health@lists.keionline.org>  
**Cc:** Diane Singhroy <diane.singhroy@keionline.org>; Andrew S. Goldman <andrew.goldman@keionline.org>  
**Subject:** [Ip-health] KEI asks the Department of Health and Human Services to adopt a policy on licensing CRISPR patents

<http://keionline.org/node/2801>

KEI asks the Department of Health and Human Services to adopt a policy on licensing CRISPR patents 6.  
June 2017 - 5:21

On June 6, 2017, Knowledge Ecology International wrote to the U.S. Department of Health and Human Services (DHHS) asking the Department to adopt a policy on the licensing of federally-funded CRISPR patented inventions. (Copy here).

<http://keionline.org/sites/default/files/CRISPR-SecPrice-6Jan2017.pdf>

In part 1, the 17 page letter reviews the importance of the CRISPR technology. Part 2 discusses the public interest in non-discriminatory licensing of CRISPR patent. In part 3, makes suggestions regarding the policies that would advance the public interest, and ensure that those inventions are "available to

REL0000023942

the public on reasonable terms” and that the licenses are designed to achieve the purposes and objectives of the Bayh-Dole Act and to maximize the benefits to taxpayers and patients.

The table of contents of the letter is as follows:

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Table of contents

Part 1. The CRISPR technology has important research and medical applications.  
Figure 1: Pipeline of CRISPR-Cas- assisted drug discovery (From Fellmann C et al.)

Part 2. There is a public interest in open, non-discriminatory licensing of CRISPR patents on reasonable terms.

1. The CRISPR patent landscape and licensing arrangements Table 1: CRISPR patent landscape Figure 2: CRISPR-CAS9 licensing agreements

2. Exclusive licenses on CRISPR are contrary to federal guidance

3. Exclusive licenses are an unnecessary and inappropriate means to incentivize research using the CRISPR platform.

4. Exclusive licenses on CRISPR patents will limit patient access.

Part 3. DHHS policy on the licensing of CRISPR patents.

Conclusion

Annex 1: NIH Sharing Policies and Related Guidance  
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The suggestions on licensing are as follows:

Part 3. DHHS policy on the licensing of CRISPR patents.

As noted in Annex 1, DHHS has adopted at least 20 statements on sharing policies and related guidance for NIH-funded research resources.

There is a pressing need for a U.S. government policy statement regarding the licensing of government-funded CRISPR inventions.

The following comments are offered to assist the DHHS in developing such a policy statement:

1. In 2001 and in subsequent agreements with the WiCell Research Institute, Inc., the NIH intervened to ensure access to non-commercial research institutions to patented inventions involving stem cells.[fn [48]] The WiCell/NIH agreement can be seen as implementing a 1999 NIH policy statement on “Sharing Biomedical Research Resources,”[fn [49]] and focused primarily on ensuring non-profit entities would be able to use stem cells for research purposes.[fn [50]]

2. The policy statement for CRISPR patents should ensure non-exclusive licensing in all fields of technology. The CRISPR technology is not a product, but a tool that can be used to create products and advance our understanding of human diseases. It is in the public interest to ensure non-discriminatory freedom to use the technology, in some cases royalty-free, and in other cases with fair and reasonable remuneration.

3. A related area concerns patents that are essential to implement standards. For many technologies, including but not limited to those involving networked information technologies or green energy technologies, so-called standards essential patents (SEPs) can impose costs on society and limit innovation, if licensed on unreasonable or discriminatory terms. Often these disputes are resolved through contracts between patent holders and Standards Developing Organizations (SDOs), with a commitment that the patent holders agree to license patents on fair, reasonable, and non-discriminatory terms, referred to as FRAND terms. The US Patent and Trademark Office (USPTO) and the U.S. Department of Justice (USDJO) have addressed this issue in a nuanced January 8, 2013 policy statement.[fn [51]]

4. In the case of the CRISPR patents, the policy should be to ensure open and non-discriminatory licensing of the patents to both nonprofit and for-profit entities.

5. The licensing of CRISPR patents to non-commercial entities for research purposes should be royalty-free, a condition met by earlier CRISPR patent holders.

6. The licensing of CRISPR patents to commercial entities may require payment of royalties, but only on FRAND terms.

7. The licensing of CRISPR patents to any entity should not have reach-through rights to subsequent patents, unless the reach-through clause is designed to benefit an entity that is creating a research commons.

8. The funding agency should require the patent holders to disclose license agreements and royalty payments, as well as the rationale for royalties charged.

9. The NIH should reserve the right to require that royalty payments be based upon only the use as a research tool, or only on final products.

. . .

#### Notes

[48] WiCell Agreement No. 02-W012B, 09042012 NIH, Amended and Restated Memorandum of Understanding between WiCell Research Institute, Inc. and Public Health Service U.S. Department of Health and Human Services.

November 2012.

<https://www.ott.nih.gov/sites/default/files/documents/pdfs/wicell-rev.pdf>

[49] National Institutes of Health. Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts. Federal Register Vol. 64, No. 246, page 72090-6. December 23, 1999.

[50] Debra Robertson, NIH sacrifices commercial rights in WiCell deal, Nature Biotechnology 19, 1001 (1 November 2001), doi:10.1038/nbt1101-1001.

[51] United States Department Of Justice And United States Patent & Trademark Office Policy Statement On Remedies For Standards-essential Patents Subject To Voluntary F/rand Commitments January 8, 2013

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James Love. Knowledge Ecology International <http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile:

+41.76.413.6584, [twitter.com/jamie\\_love](https://twitter.com/jamie_love)

---

Ip-health mailing list

[ip-health@lists.keionline.org](mailto:ip-health@lists.keionline.org)

[http://lists.keionline.org/mailman/listinfo/ip-health\\_lists.keionline.org](http://lists.keionline.org/mailman/listinfo/ip-health_lists.keionline.org)

---

**From:** Greene, Jaime (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E06E39F0BCD34511A92DF20C5DC8722A-GREENEJAIME]  
**Sent:** 4/22/2019 2:10:36 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** response to KEI on A-058-2019  
**Attachments:** A-058-2019 ResponseToKei.docx; EXAMPLE NCIResponsetoKEI\_7.23.2018\_83FR30448.pdf; Morphix license

Hi Mark,

Attached please find a response to KEI. Their comments were nearly identical to the ones Rose Freele received on her Atara application, [REDACTED] b5

[REDACTED] b5 I attached Rose's response for your reference, as well as KEI's comments on my application.

Richard is fine with the attached response to KEI, but he requested that you review it, too, and let me know if you have any comments.

Please let me know if you have any comments to add.

Thanks,

Jaime

Jaime Meredith Greene, M.S.  
Senior Technology Transfer Manager  
NCI Technology Transfer Center

**Note:** This email may contain confidential information. If you are not the intended recipient, any disclosure, copying or use of this email or the information enclosed therein is strictly prohibited, and you should notify the sender for return of any attached documents

REL0000023943

**b5**



National Institutes of Health  
National Cancer Institute  
Technology Transfer Center  
8490 Progress Drive  
Riverside 5 building, Suite 400  
Frederick, MD 21701  
Phone (301) 624-8775  
FAX (301) 631-3033

*via email only*

July 23, 2018

James Love  
Knowledge Ecology International (KEI)  
1621 Connecticut Avenue, Suite 500,  
Washington DC 20009

RE: Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin  
Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer (83 FR 30448)

Dear Mr. Love,

Thank you for providing us with your comments in response to the Federal Register Notice of the proposed license to Atara Biotherapeutics (Atara) by the National Cancer Institute (NCI). We have reviewed and considered all of your comments and the specific recommendations you provided regarding terms to be included in the license related to the pricing of products, the term of exclusivity, the exclusivity and access in developing countries, and the transparency of the licensee's development through annual reporting.

With respect to your comments regarding the pricing of products in the US and developing countries, the NIH has not included terms related to pricing in its licenses for many years. The reasons for this are well established and are publicly available.

With respect to your comments regarding transparency of information regarding clinical trial outlays and research and development costs by the licensee, these are business confidential information that, under the licensing statute, cannot be disclosed.

Sincerely,

Rose M. Frecl, Ph.D.  
Senior Technology Transfer Manager  
NCI Technology Transfer Center



---

**From:** James Love [james.love@keionline.org]  
**Sent:** 2/20/2019 11:46:15 PM  
**To:** Greene, Jaime (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e06e39f0bcd34511a92df20c5dc8722a-greenejaime]; Luis Gil Abinader [luis.gil.abinader@keionline.org]  
**Subject:** Morphix license  
**Attachments:** Comments on NIH License to Morphix on CD47 for solid tumors Feb2019 .pdf

Dear Jaime Greene,

Attached are KEI comments on the Prospective Grant of an Exclusive Patent License: Use of the CD47 Phosphorodiamidate Morpholino Oligomers for the Treatment, Prevention, and Diagnosis of Solid Tumors to Morphix Biotherapeutics ("Morphix") located in Boston, MA.

Jamie

--

James Love. Knowledge Ecology International  
<http://www.keionline.org>  
[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

February 20, 2019

Jaime Greene  
Senior Licensing and Patenting Manager  
NCI Technology Transfer Center  
9609 Medical Center Drive, RM 1E530 MSC 9702  
Bethesda, MD 20892-9702  
Rockville, MD 20850-9702

Via email: [greenejaime@mail.nih.gov](mailto:greenejaime@mail.nih.gov)

Re: 84 FR 1764. Prospective Grant of an Exclusive Patent License: Use of the CD47 Phosphorodiamidate Morpholino Oligomers for the Treatment, Prevention, and Diagnosis of Solid Tumors to Morphiex Biotherapeutics ("Morphiex") located in Boston, MA.

Dear Jaime Greene,

We are writing to express our opposition to an exclusive license on the patent portfolio described in 84 FR 1764, regarding the "Use of the CD47 Phosphorodiamidate Morpholino Oligomers for the Treatment, Prevention, and Diagnosis of Solid Tumors" to Morphiex Biotherapeutics.

Morphiex Biotherapeutics, Inc, was registered in Delaware on February 27, 2018, and is located in Boston, Massachusetts. According to its website, this company "is developing phosphorodiamidate morpholino oligomers (PMOs) for the treatment of cancer."<sup>1</sup> Morphiex further notes in their website that their lead candidate, MBT-001, "was developed at the National Cancer Institute (NCI) at the National Institutes of Health (NIH)."<sup>2</sup>

The CEO of Morphiex is Anthony Schwartz, PhD. According to his bio in the Morphiex website, Dr. Schwartz worked at the National Institutes of Health (NIH) National Cancer Institute (NCI) "to advance Morphiex's lead CD47 asset, MBT-001, into the clinic."<sup>3</sup> Dr. Schwartz worked four years at the NIH/NCI and left on December 2017<sup>4</sup>, shortly before Morphiex was registered.

A Federal Register notice published on May 15, 2018, 83 FR 22501, noticed the prospective grant of another exclusive license to Morphiex. That notice covered a portfolio comprised of 17 patent documents, a territory that "may be worldwide" and a field of use that may be limited to the use of CD47 "for the treatment, prevention, and diagnosis of hematological cancers (e.g. lymphoma, leukemia, multiple myeloma), excluding uses in combination with radiotherapy."

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<sup>1</sup> [http://morphiex.com/site/?page\\_id=6](http://morphiex.com/site/?page_id=6)

<sup>2</sup> [http://morphiex.com/site/?page\\_id=6](http://morphiex.com/site/?page_id=6)

<sup>3</sup> <http://morphiex.com/site/team/>

<sup>4</sup> <https://www.linkedin.com/in/anthony schwartzphd/>

The current Federal Register notice (84 FR 1764) published on February 5, 2019, covers the same 17 patent documents as well as a territory that “may be worldwide”, but a different field of use that may be limited to the use of CD47 “for the treatment, prevention, and diagnosis of solid tumors, excluding uses in combination with radiotherapy.”

Therefore, what the prospective exclusive license noticed in 84 FR 1764 will do is expand a previous exclusive license that covered the use of CD47 on hematological cancers to now include the use of these inventions in the treatment, prevention and diagnosis of solid tumors.

The Federal Register notice 84 FR 1764 merely cites the previous prospective exclusive license to Morphix, suggesting that the current notice “is in reference to a previous notice 83 FR 22501 [...]” and describing the field of use of that previous license. Despite that general mention, the NIH has not provided an explanation of how the NIH has determined that expanding the exclusive license granted to this company is a reasonable and adequate incentive to induce development, given that Morphix already has existing obligations to bring the inventions to practical application for for the treatment, prevention, and diagnosis of hematological cancers.

The Federal Register notice 84 FR 1764 describes the CD47 technology as follows:

This technology concerns CD47, originally named integrin-associated protein, which is a receptor for thrombospondin-1 (TSP1), a major component of platelet  $\alpha$ -granules from which it is secreted on platelet activation. A number of important roles for CD47 have been defined in regulating the migration, proliferation, and survival of vascular cells, and in regulation of innate and adaptive immunity. Nitric Oxide (NO) plays an important role as a major intrinsic vasodilator, and it increases blood flow to tissues and organs. Disruption of this process leads to peripheral vascular disease, ischemic heart disease, stroke, diabetes and many more significant diseases. The inventors have discovered that TSP1 blocks the beneficial effects of NO and prevents it from dilating blood vessels and increasing blood flow to organs and tissues. Additionally, they discovered that this regulation requires TSP1 interaction with its cell receptor, CD47. These inventors have also found that blocking TSP1-CD47 interaction through the use of antisense morpholino oligonucleotides, peptides or antibodies have several therapeutic benefits including the treatment of cancer.

Before the NIH grants a new or expanded license to Morphix, we expect the NIH to seek the advice of the Department of Justice antitrust authorities, as is required by

40 U.S. Code § 559 - Advice of Attorney General with respect to antitrust law.

In such a review, the NIH should note that the expanded field of use will create a legal monopoly on the use of the inventions for the treatment, prevention, and diagnosis of solid tumors, and foreclose non-exclusive licenses for these uses. The NIH should also make it clear

that it has the responsibility under 35 USC § 209(a) to limit the scope of rights to that which are reasonably necessary to induce investment, and that among the options the NIH as are to limit the field of use or the years of exclusivity, and demonstrate to DOJ that the NIH as address this restriction in good faith.

In the event that the NIH decides to grant this exclusive license, we ask that the following safeguards be placed on the license.

1. **Price discrimination.** Any drug or other medical technology using the patented invention should be available in the United States at a price that does not exceed the median price in the seven largest economies by GDP that have at least 50 percent of the GNI per capita as the United States, using the World Bank Atlas method. This is a modest safeguard.
2. **Low and middle income countries.** The exclusive license does not extend to countries with a per capita income less than 30 percent of the United States, in order to ensure that the patents do not lead to restricted and unequal access in developing countries. If the NIH rejects this suggestion, it needs to provide something that will give effect to the policy objective in the “United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy,” which states the following: “PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries.” There is ample evidence that federally funded inventions for the treatment of cancer are not widely available in developing countries. Examples of the access problems include Xtandi and the two new CAR T treatments, to mention a few.
3. **Global registration and affordability.** The license should require Morphix to disclose the steps it will take to enable the timely registration and availability of the drug at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC)/ World Health Organization (WHO), either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.
4. **Medicines Patent Pool.** The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the drug from competitive suppliers, including technology transfer, in developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the drug.
5. **Years of exclusivity.** We propose the license reduce the years of exclusivity when revenues are large. The NIH has many options, including by providing an option for non-exclusive licensing, such as was done in the ddl case. We propose that the

exclusivity of the license be reduced when the global cumulative sales from products or services using the inventions exceed certain benchmarks. For example, the period of exclusivity in the license could be reduced by one year for every \$500 million in global cumulative revenue after the first one billion in global sales. This request is consistent with the statutory requirements of 35 USC § 209, which requires that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.”

6. **Transparency of R&D outlays.** The licensee should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product or service that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We will note that this is not a request to see a company business plan or license application. We are asking that going forward the company be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 U.S.C. § 209, that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application.” Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to practical application.

Sincerely,

James Love  
Knowledge Ecology International (KEI)  
1621 Connecticut Avenue, Suite 500  
Washington, DC 20009  
james.love@keionline.org

Luis Gil Abinader  
Knowledge Ecology International (KEI)

---

**From:** Berkley, Dale (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE461C29F5045A49F0ADF82CAAA2F31-BERKLEYD]  
**Sent:** 6/29/2018 2:39:19 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: 83 FR 30448, Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

b5

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**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Friday, June 29, 2018 10:17 AM  
**To:** Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>  
**Subject:** FW: 83 FR 30448, Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

b5

**From:** Freel, Rose (NIH/NCI) [E]  
**Sent:** Friday, June 29, 2018 9:26 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
**Subject:** FW: 83 FR 30448, Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

Hi Mark,

See email below from KEI regarding a FR Notice for intent to grant. Let me know when you have time to discuss.

Thanks!  
Rose

--  
Rose Santangelo Freel, Ph.D.  
Technology Transfer Manager  
**National Cancer Institute**  
P 301-624-1257 | [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

**From:** James Love [<mailto:james.love@keionline.org>]  
**Sent:** Thursday, June 28, 2018 4:04 PM  
**To:** Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)>  
**Cc:** Claire Cassedy <[claire.cassedy@keionline.org](mailto:claire.cassedy@keionline.org)>  
**Subject:** 83 FR 30448, Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

Rose M. Freel, Ph.D.,  
Licensing and Patenting Manager,  
NCI Technology Transfer Center,  
8490 Progress Drive, Suite 400, Frederick, MD 21701;  
Email: [rose.freel@nih.gov](mailto:rose.freel@nih.gov).

REL0000023947

Dear Dr  
Freel,

Has the technology referred to in 83 FR 30448, regarding Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer, been subject to any clinical trials (1) funded by the NIH, or (2) funded by any other party?

This information is useful for KEI in preparing our comments on the license.

Jamie

--

James Love. Knowledge Ecology International

<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, [twitter.com/jamie\\_love](https://twitter.com/jamie_love)

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**From:** Plude, Denise (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=PARKSDE]  
**Sent:** 5/1/2017 5:01:56 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]  
**CC:** Jorgenson, Lyric (NIH/OD) [E] [/O=NIH/OU=Nihexchange/cn=recipients/cn=jorgensonla]; Fennington, Kelly (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=FENNINGTONKNEW]  
**Subject:** RE: WF 357204 - Response Creation due 5/1

Hi Mark, is this almost ready?

---

**From:** Plude, Denise (NIH/OD) [E]  
**Sent:** Monday, May 01, 2017 10:15 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>  
**Subject:** RE: WF 357204 - Response Creation due 5/1  
**Importance:** High

This is due today. Please send by noon so Lyric has time to review before sending to Exec Sec.

---

**From:** Plude, Denise (NIH/OD) [E]  
**Sent:** Monday, April 24, 2017 2:52 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>  
**Cc:** Wertz, Jennifer (NIH/OD) [E] <wertzj@od.nih.gov>  
**Subject:** WF 357204 - Response Creation due 5/1

**Work Folder Information**

**Work Folder:** WF 357204

**Process:** Response Creation

**Program Analyst:** Hurlebaus, Lisa (NIH/OD) [E]

**Due Date:** May 01, 2017

**WF Subject:** OS assignment. KEI & UACT write about the prostate cancer drug, Xtandi (enzalutamide). Asks the Government to reconsider the decision not to use the 'march-in' rights, under the Bayh-Dole Act, for this excessively-priced drug. (AS-760889)

**IC:** od\_osp

**From:** Goldman, Andrew

**To:** Price, TomMatis, Jim

**Remarks:** OS assignment. Note to OER & OSP: Please work together to prepare Direct Reply response. You should decide/recommend who should sign draft response (Dr. Lauer or Dr. Wolinetz; or someone else?). Please provide draft response to Exec Sec in DDRMS by 12:00pm, Monday, May 1, for OD clearances. Thanks very much, Lisa Hurlebaus



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**From:** Girards, Richard (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6F43C30C4A364463BF5B2C134225B7F0-GIRARDSRT]  
**Sent:** 11/2/2017 3:50:27 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: paper and blog of interest  
**Attachments:** Capstone Project submission as of 02 Nov 2017.docx

Dear Mark-

Attached is a new draft, updated in light of your comments of last week.

Let's discuss further, as planned, on Tues- thanks!

-Rick

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Wednesday, October 25, 2017 6:36 PM  
**To:** Girards, Richard (NIH/NCI) [E] <richard.girards@nih.gov>  
**Subject:** RE: paper and blog of interest

Good draft. I made a few comments as I read through it. How would you like to proceed? I could read through it more thoroughly and then we could meet/talk about it for a few final polishes perhaps. You want to do that in say 2 weeks? Is this about the final length?

**From:** Girards, Richard (NIH/NCI) [E]  
**Sent:** Wednesday, October 25, 2017 5:18 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** RE: paper and blog of interest

Dear Mark-

Attached is a draft- thanks again for agreeing to be a mentor on this project!

Please do let me know if you have any questions or comments. I have discussed a prior draft with Steve Ferguson and incorporated his comments into the attached draft.

In terms of timing, I'll have to submit a final work product about the first week of December- I've budgeted the month of November for you and me to update (if necessary) this draft.

-Rick

Richard T. Girards, Jr., Esq., MBA  
National Institutes of Health  
NCI Technology Transfer Center  
9609 Medical Center Drive, Room 1E508 MSC 9702  
Rockville, MD 20850-9702 for UPS/FedEx/visitors  
Bethesda, MD 20892-9702 for U.S. Mail  
[richard.girards@nih.gov](mailto:richard.girards@nih.gov)  
Phone: 240-276-6825

REL0000023949

Fax: 240-276-5504  
<http://ttc.nci.nih.gov>

---

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Friday, September 29, 2017 11:09 AM  
**To:** Girards, Richard (NIH/NCI) [E] <[richard.girards@nih.gov](mailto:richard.girards@nih.gov)>  
**Subject:** RE: paper and blog of interest

Looks good. A few suggestions. Also please be careful to make clear that this is done as part of your outside activity not official work activity. Employees cannot advocate for legislation, and these are your personal ideas not those of NIH or NCI. That is not to say they would not be useful to NIH, just not official work product.

**From:** Girards, Richard (NIH/NCI) [E]  
**Sent:** Friday, September 29, 2017 9:44 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Subject:** RE: paper and blog of interest

Dear Mark-

Any thoughts as to the below?

Thanks.

-Rick

**From:** Girards, Richard (NIH/NCI) [E]  
**Sent:** Monday, September 25, 2017 9:25 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[RohrBauM@OD.NIH.GOV](mailto:RohrBauM@OD.NIH.GOV)>  
**Subject:** RE: paper and blog of interest

Thanks again, Mark- I greatly appreciate it.

In terms of a defined "mission/deliverables statement" for my capstone project, I have formulated the following:

**b6**

Would this type of work product be useful to your office ... in addition, do you have any comments as to the proposed scope?

REL0000023949

-Rick

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Thursday, September 21, 2017 12:26 PM  
**To:** Girards, Richard (NIH/NCI) [E] <[richard.girards@nih.gov](mailto:richard.girards@nih.gov)>  
**Subject:** paper and blog of interest

Rick:

Here is a link to the CellPro march-in I mentioned. <http://scholarship.law.berkeley.edu/btlj/vol14/iss3/7/>

Interesting new blog about research impact. I was thinking about it in terms of some of the discussion near the end as to how we communicate with greater society about impacts of what we are doing. How do we communicate with the public about these issues of the role of NIH. Just a thought. <http://www.sciencemetrics.org/research-impact-now/>

Mark  
Mark L. Rohrbaugh, Ph.D., J.D.  
Special Advisor for Technology Transfer  
Director, Division of Technology Transfer and Innovation Policy  
Office of Science Policy  
Office of the Director  
National Institutes of Health

**b6**

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**b6**

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**From:** Rodriguez, Richard (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8092CB5394E04733AC0D4D84D25F65E5-RODRIGR]  
**Sent:** 9/21/2017 5:42:53 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** KEI Response  
**Attachments:** A-325-2017

Hi Mark,

I'm following up on this request for input on a NCI response to a KEI comment. Karen Maurey mentioned this topic to me in a meeting this morning, and that you had commented [REDACTED] b5 [REDACTED] b5 (TDC-Short meeting I think). Also, this relates to what I wrote you about this morning, and so I just want to make sure we are all on the same page.

Thanks,

Richard

---

**RICHARD U. RODRIGUEZ, M.B.A.**  
Associate Director  
Patent Agent

Technology Transfer Center  
National Cancer Institute  
National Institutes of Health  
9609 Medical Center Drive, Rm 1E530  
Bethesda, MD 20892-9702 (for business mail)  
Rockville, MD 20850-9702 (for courier service/visitors)  
Phone (Main Office): 240-276-5530  
Direct phone: 240-276-6661  
Fax 240-276-5504  
[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)

<https://techtransfer.cancer.gov>

"Start by doing what's necessary; then do what's possible; and suddenly you are doing the impossible" - Francis of Assisi

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REL0000023950

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**From:** Greene, Jaime (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E06E39F0BCD34511A92DF20C5DC8722A-GREENEJAIME]  
**Sent:** 9/15/2017 5:10:21 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** A-325-2017  
**Attachments:** KEI letter Nanobernetics-NIH-5Sept2017-82fr41970.pdf; Response to KEI.docx  
  
**Flag:** Follow up

Dear Mark,

Attached please find a draft response to KEI's objection to my intent to grant an exclusive to Nanobernetics. I have not received any other objections.

Please take a look at the response, and let me know if you have any comment.

I'd appreciate a response by September 20, 2017, the closing date of the FR Notice.

Thanks,

Jaime

Jaime Meredith Greene, M.S.  
Senior Technology Transfer Manager  
NCI Technology Transfer Center  
9609 Medical Center Drive  
Rockville, MD 20850  
Telephone: 240-276-6633  
Email: [greenajaime@mail.nih.gov](mailto:greenajaime@mail.nih.gov)

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September 5, 2017

Jaime M. Greene  
Senior Licensing and Patenting Manager  
NCI Technology Transfer Center  
9609 Medical Center Drive  
Rm. 1E530 MSC 9702  
Bethesda, MD 20892-9702  
+1 (240)-276-5530  
Facsimile: +1 (240)-276-5504  
Via email: [greenajaime@mail.nih.gov](mailto:greenajaime@mail.nih.gov)

Re: KEI questions and initial comments on Prospective Grant of an Exclusive Patent License:  
Apparatus for Microarray Binding Sensors Having Biological Probe Materials Using Carbon  
Nanotube Transistors to Nanobernetics, LLC ("Nanobernetics") , as noticed in the Federal  
Register, 82 FR 41970.

Dear Jaime Greene,

Having seen a copy of the Federal Register notice on the proposed license to Nanobernetics, LLC, KEI has several questions and offers initial comments on the proposed license.

**Questions.**

1. Is this a start-up license?
2. What is the proposed term of the license?
3. What is the proposed royalty rate on the license?
4. Does the NIH have any other contracts, licenses, CRADAs or other agreements with the firm or any of its officers or founders?
5. LinkedIn lists a PhD student at the University of Maryland, College Park (UMCP) as the only employee for this firm, and the web page gives the names of just two persons, both graduate students at UMCP. Why does the NIH believe the firm can bring the invention to practical application, and does the NIH expect the firm will primarily market the patent rights to third parties, or develop the technology itself?
6. Will the license comply with the norms on pricing included in the directive in the U.S. Senate Armed Services Committee report for the National Defense Authorization Act for fiscal year 2018?

## Initial Comments on the Proposed License

1. KEI suggests that the license include language to address the pricing norm proposed by the U.S. Senate Armed Services Committee report for the National Defense Authorization Act for fiscal year 2018.

One of the subject patents is U.S. Patent 8,017,938 (Application No. 11/723,369), filed 19 March 2007, titled "Apparatus for Microarray Binding Sensors Having Biological Probe Materials Using Carbon Nanotube Transistors." According to the published patent, "The work leading up to the present invention was funded, at least in part, by NSA under Grant H9823004C0470." We note the NSA is an agency of the Department of Defense.

On page 173 of Senate Report 115-125, titled "*National Defense Authorization Act for Fiscal Year 2018, Report to accompany S. 1519*," there is a directive on the "Licensing of federally owned medical inventions", which reads as follows:

The committee directs the Department of Defense (DOD) to exercise its rights under sections 209(d)(1) or 203 of title 35, United States Code, to authorize third parties to use inventions that benefited from DOD funding whenever the price of a drug, vaccine, or other medical technology is higher in the United States than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States.

We suggest that the following language be included in the license:

[The party obtaining the license] agrees to make the product available to the public in the U.S. at publicly disclosed prices no higher than the median price charged in Canada plus the seven countries with the largest GDP, which have per capita incomes of at least half that of the U.S.

2. Address and make more concrete the expectations regarding the obligation to technologies "available to the public on reasonable terms."

The company obtaining the license should disclose the steps it will undertake to make the benefits of the invention "available to the public on reasonable terms," as is required by the Bayh Dole Act per definition under 35 U.S.C. § 201(f). If this obligation is seen as global, then the following text would be appropriate:

[The party obtaining the license] agrees to disclose the steps it will take to enable the registration and availability of the product at an affordable price in every country with a demonstrated need, either by supplying a country directly at an affordable, publicly

disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.

3. Access to the technology in developing countries.

We oppose making the license exclusive worldwide. The NIH should reserve the right to issue licenses to third parties, including the Medicines Patent Pool, in countries that have a per capita income less than half that of the U.S.

Sincerely,

**b5**

**b5**



---

**From:** Soukas, Peter (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B1F6020157AC47948C6E34166B78E433-SOUKASP]  
**Sent:** 1/30/2019 8:53:55 PM  
**To:** Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Frisbie, Suzanne (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c402740ceaad4d4f97a8c28f16fbb349-frisbies]; Williams, Richard (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5f89fe4d27a43abb936bb20efeca3b9-rwilliams]; Puglielli, Maryann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f53ceacaf754875a948081bac5cc66a-pugliellim]  
**Subject:** Re: KEI Response Letter  
**Attachments:** Response to KEI J Love Comments NIAID Final.docx

Dear Dale and Mark,

We hope everything is going well with you. Thank you for the productive conversation last week.

Attached please find a further draft letter for your review and/or approval.

Please contact us if you have any additional questions. Thank you once again for your help.

Peter Soukas  
Phone: 301-594-8730  
Email: [ps193c@nih.gov](mailto:ps193c@nih.gov)

---

**From:** Berkley, Dale (NIH/OD) [E]  
**Sent:** Wednesday, January 23, 2019 12:51 PM  
**To:** Mowatt, Michael (NIH/NIAID) [E]; Rohrbaugh, Mark (NIH/OD) [E]; Frisbie, Suzanne (NIH/NIAID) [E]; Soukas, Peter (NIH/NIAID) [E]; Williams, Richard (NIH/NIAID) [E]; Puglielli, Maryann (NIH/NIAID) [E]  
**Subject:** RE: KEI Response Letter

**b5**

Dale D. Berkley, Ph.D., J.D.  
Office of the General Counsel, PHD, NIH Branch  
Bldg. 31, Rm. 47  
Bethesda, MD 20892  
301-496-6043  
301-402-2528(Fax)

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-----Original Message-----

From: Mowatt, Michael (NIH/NIAID) [E] <[mmowatt@niaid.nih.gov](mailto:mmowatt@niaid.nih.gov)>  
Sent: Tuesday, January 22, 2019 12:53 PM  
To: Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Frisbie, Suzanne (NIH/NIAID) [E] <[suzanne.frisbie@nih.gov](mailto:suzanne.frisbie@nih.gov)>; Soukas, Peter (NIH/NIAID) [E] <[peter.soukas@nih.gov](mailto:peter.soukas@nih.gov)>; Williams, Richard

REL0000023951

(NIH/NIAID) [E] <rwilliams@niaid.nih.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>  
Cc: Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Mowatt, Michael (NIH/NIAID) [E]  
<mmowatt@niaid.nih.gov>  
Subject: RE: KEI Response Letter

Team,

I ran into Dale just now at NIH.

b5

b5 We shouldn't need more than 15 or 30 minutes tomorrow.

Thanks Dale and everyone,

Mike

-----Original Message-----

From: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
Sent: Tuesday, January 22, 2019 12:24 PM  
To: Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>  
Cc: Frisbie, Suzanne (NIH/NIAID) [E] <suzanne.frisbie@nih.gov>; Soukas, Peter (NIH/NIAID) [E]  
<peter.soukas@nih.gov>; Williams, Richard (NIH/NIAID) [E] <rwilliams@niaid.nih.gov>; Puglielli, Maryann  
(NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>  
Subject: Re: KEI Response Letter

Just saw this. Do you have time now?

Sent from my iPhone

> On Jan 22, 2019, at 11:59 AM, Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov> wrote:

>

> 1-888-370-7168

> Leader - 9665858

> Participant - 1625866

>

>

> Thanks, Mary.

>

> This one is a priority, so please squeeze it in this week. Tomorrow afternoon?

>

>

>

>

> Dear Mary,

>

> We are just following up, we hope everything is going well with you.

>

> Does Mike have any time this week to discuss these issues with Mark Rohrbaugh and Dale Berkley?

>

> We look forward to a meeting invitation soon.

>

> Thank you.

>

> Peter

> <meeting.ics>

REL0000023951

**b5**

**b5**

**b5**

---

**From:** Bonham, Valerie (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DD4040EAA26541A8B30FC274E52ABA59-BONHAMVA]  
**Sent:** 4/22/2019 11:12:36 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** Fwd: Good morning OER -- from 144  
**Attachments:** ATT00001.htm; ATT00002.htm; ATT00003.htm; Commerce Department and March-in rights drug pricing.pdf; ATT00004.htm

Politico story, just in case....

Sent from my iPad

Begin forwarded message:

**From:** "Lauer, Michael (NIH/OD) [E]" <[michael.lauer@nih.gov](mailto:michael.lauer@nih.gov)>  
**To:** "OD-OER All" <[OD-OERAll@mail.nih.gov](mailto:OD-OERAll@mail.nih.gov)>  
**Cc:** "Lauer, Michael (NIH/OD) [E]" <[michael.lauer@nih.gov](mailto:michael.lauer@nih.gov)>  
**Subject:** Good morning OER -- from 144

Good morning OER!

- Two articles on MD Anderson, NIH, and the Chinese Thousand Talents and related programs – one in *Science* and one in the *Houston Chronicle*.
- *Scientific American* [article](#) on declines in both explicit and implicit bias over time. Thanks to Sally Amero.
- Politico news story on Commerce Department's position against using "March-in" rights to control drug prices. Thanks so Adrienne Hallett.

Have a great day!

Best, Mike

Michael S Lauer, MD  
NIH Deputy Director for Extramural Research  
One Center Drive, Building 1, Room 144  
Bethesda, MD 20892  
301-496-1096  
[Michael.Lauer@nih.gov](mailto:Michael.Lauer@nih.gov)

**Subject:** FW: Prescription Pulse: Commerce department expected to slash march-in rights for drugs —  
**Date:** Friday, April 19, 2019 at 10:46:23 AM Eastern Daylight Time  
**From:** Hallett, Adrienne (NIH/OD) [E]  
**To:** NIH Director's Executive Committee  
**Priority:** High

Flagging this Commerce report on march-in rights

## **COMMERCE REPORT: MARCH-IN RIGHTS SHOULDN'T BE USED AS DRUG PRICE CONTROL TOOL**

— Advocates of lower drug costs are concerned that the Department of Commerce's National Institute of Standards and Technology will finalize a little-noticed [green paper](#) that recommends against the government exercising its "march-in" rights to help lower the cost of medicines. NIST said the final paper should be released next week. It will be reviewed by an interagency panel, and regulatory changes could follow. Many Democrats in Congress have raised the possibility of using march-in rights or similar authority to revoke patent rights or marketing exclusivity on certain drugs. They've tried to use the idea as a stick to encourage companies to cooperate on drug price negotiations.

**The background:** The 1980 Bayh-Dole Act laid out a pathway to freely transfer inventions and patent rights resulting from federally funded research to non-government organizations, so they could be commercialized. But the law outlined limited circumstances where the government could "march in" and let other parties produce the patented invention, including when health and safety needs were not being satisfied in a reasonable way. Groups like Doctors Without Borders and Knowledge Ecology International have petitioned NIH to claim that the high cost of a medication can satisfy the definition of an unmet need. So far, NIH has never agreed with this argument.

Now, NIST is recommending changes to Bayh-Dole Act regulations to ensure march-in rights are never used to control the price of a good, specifically pharmaceuticals.

**Advocates push back:** Doctors Without Borders has strongly objected to the idea. "Agencies relying on public funds to develop life-saving medicines should not seek to curtail the public's right to appropriate, affordable access to products developed with public support by this proposed unilateral regulatory action," the group wrote in [comments on the green paper](#). The change it proposes "goes against the stated goals of the administration to lower drug prices and calls by more than 50 members of Congress to use march-in rights to address 'soaring' pharmaceutical prices." The group notes that a [March 2018 study](#) found NIH funding contributed to each of the 210 new drugs approved by FDA from 2010 through 2016.

Eleven groups including Doctors Without Borders, Public Citizen, Social Security Works and the Yale Global Health Justice Partnership [wrote Congress](#) earlier this month urging lawmakers to oppose the change. They also raised concerns that another suggestion in the report could harm access to affordable medicines. This



change would narrow the government's royalty-free rights to inventions whose development it funded, to exclude situations where the government isn't directly using or consuming the patented good. This would prevent the government from using royalty-free rights to provide affordable drugs in Medicare or other government programs.

"At a time when drug prices have become increasingly unaffordable for American patients, the administration's proposals in the NIST paper outline provisions designed to protect pharmaceutical companies that sell expensive treatments, and exempt them from obligations to ensure that treatments are affordable and accessible," the letter says.

**From:** POLITICO Pro Health Care <[politicoemail@politicopro.com](mailto:politicoemail@politicopro.com)>

**Sent:** Friday, April 19, 2019 7:03 AM

**To:** Arbes, Sarah (HHS/ASL) <[Sarah.Arbes@hhs.gov](mailto:Sarah.Arbes@hhs.gov)>

**Subject:** Prescription Pulse: Commerce department expected to slash march-in rights for drugs — CMS takes aim at manufacturer coupons — Judge rejects DOJ dismissal of pharma kickback suit

[View online version](#)

# PRESCRIPTIONPULSE

04/19/2019 07:00 AM EDT

By SARAH KARLIN-SMITH ([skarlin@politico.com](mailto:skarlin@politico.com); [@SarahKarlin](#)), SARAH OWERMOHLE ([sowermohle@politico.com](mailto:sowermohle@politico.com); [@owermohle](#))

*With help from Allie Bice*

## ON TAP

— **March-in rights aren't a drug price control tool, a final Department of Commerce Report is expected to declare this week.** Many patient advocacy groups aren't happy.

— **CMS takes aim at copay coupons in final Obamacare rule.** The changes should discourage use of manufacturer coupons.

— **Judge rejects Justice Department attempt to dismiss lawsuit charging drug company use of nurse educators.** It's one of several similar suits that DOJ wants to shoo away.



**Happy Friday and welcome back to Prescription PULSE** where we were intrigued to learn that Columbia University researcher have already created embryos with genetic material from three people, even though U.S. law prevents them from being transferred into a woman's uterus (H/T [Stat news](#)). Send interesting stories, pharma news and tips to Sarah Karlin-Smith ([skarlin-smith@politico.com](mailto:skarlin-smith@politico.com) or [@SarahKarlin](#)) and Sarah Oweremohle ([soweremohle@politico.com](mailto:soweremohle@politico.com) or [@oweremohle](#)). See you Tuesday!

## DRUG PRICING

### **COMMERCE REPORT: MARCH-IN RIGHTS SHOULDN'T BE USED AS DRUG PRICE**

**CONTROL TOOL** — Advocates of lower drug costs are concerned that the Department of Commerce's National Institute of Standards and Technology will finalize a little-noticed [green paper](#) that recommends against the government exercising its "march-in" rights to help lower the cost of medicines. NIST said the final paper should be released next week. It will be reviewed by an interagency panel, and regulatory changes could follow. Many Democrats in Congress have raised the possibility of using march-in rights or similar authority to revoke patent rights or marketing exclusivity on certain drugs. They've tried to use the idea as a stick to encourage companies to cooperate on drug price negotiations.

**The background:** The 1980 Bayh-Dole Act laid out a pathway to freely transfer inventions and patent rights resulting from federally funded research to non-government organizations, so they could be commercialized. But the law outlined limited circumstances where the government could "march in" and let other parties produce the patented invention, including when health and safety needs were not being satisfied in a reasonable way. Groups like Doctors Without Borders and Knowledge Ecology International have petitioned NIH to claim that the the high cost of a medication can satisfy the definition of an unmet need. So far, NIH has never agreed with this argument.

Now, NIST is recommending changes to Bayh-Dole Act regulations to ensure march-in rights are never used to control the price of a good, specifically pharmaceuticals.

**Advocates push back:** Doctors Without Borders has strongly objected to the idea. "Agencies relying on public funds to develop life-saving medicines should not seek to curtail the public's right to appropriate, affordable access to products developed with public support by this proposed unilateral regulatory action," the group wrote in [comments on the green paper](#). The change it proposes "goes against the stated goals of the administration to lower drug prices and calls by more than 50 members of Congress to use march-in rights to address 'soaring' pharmaceutical prices." The group notes that a [March 2018 study](#) found NIH funding contributed to each of the 210 new drugs approved by FDA from 2010 through 2016.

Eleven groups including Doctors Without Borders, Public Citizen, Social Security Works and the Yale Global Health Justice Partnership wrote Congress earlier this month urging lawmakers to oppose the change. They also raised concerns that another suggestion in the report could harm access to affordable medicines. This change would narrow the government's royalty-free rights to inventions whose development it funded, to exclude situations where the government isn't directly using or consuming the patented good. This would prevent the government from using royalty-free rights to provide affordable drugs in Medicare or other government programs.

"At a time when drug prices have become increasingly unaffordable for American patients, the administration's proposals in the NIST paper outline provisions designed to protect pharmaceutical companies that sell expensive treatments, and exempt them from obligations to ensure that treatments are affordable and accessible," the letter says.

**2020 OBAMACARE RULE TAKES AIM AT DRUG INDUSTRY COUPONS** — CMS finalized an Obamacare marketplace rule provision that should limit the use of drug industry coupons, in an effort to control medicine costs and expand the use of generic medicine in ACA plans. The rule will let insurers in 2020 exclude manufacturer coupons from counting towards a patient's annual limitation on cost sharing if a medically appropriate generic drug is available. It applies to individual market, small group, large group and self-insured group health plans to the extent permitted by applicable state law.

CMS decided not to finalize part of the 2020 rule that would have allowed insurers to not count other kinds of cost-sharing toward a patient's annual out-of-pocket limit if the beneficiary insisted on a brand drug when an appropriate generic was available. It also dropped a proposal that would have allowed insurers to adopt mid-year formulary changes, to incentivize greater use of generic medicines. More for Pros here.

**CAUTION URGED ON ARBITRATION** — House Speaker Nancy Pelosi's office and the White House have been talking drug pricing, including an idea to use arbitration as a way to help lower the cost of certain high-cost medicines. The idea has angered some on the left who see the plan as a retreat from bolder Democratic proposals to allow for government negotiation of all drugs in Medicare. The plan may not go over well with many Republicans either, albeit for different reasons.

Douglas-Holtz Eakin, president of the American Action Forum and former senior official in the George W. Bush administration, wrote this week that any use of arbitration "should be extremely limited," with restricted arbiter authority, because the process is a departure from market-based mechanisms for determining costs. "The potential for negative fallout is enormous," Eakin wrote, particularly if every new, expensive sole-source drug ends up in arbitration. He also worries that

political motives could sway the arbiter's decision. Read his full commentary [here](#).

**There's a new POLITICO newsletter in town.** Authored by Cristiano Lima, and Zack Stanton, POLITICO's Westeros Playbook is the must-read guide to what's happening in the final season of Game of Thrones. [Sign up](#) to receive POLITICO Westeros Playbook every Monday for the duration of the final season.

## IN THE COURTS

**JUDGE CHIDES JUSTICE DEPT AS SHE DENIES PHARMA LAWSUIT DISMISSAL** — A federal judge this week rejected the federal government's efforts to dismiss a lawsuit alleging that Belgian drugmaker UCB used illegal kickback schemes with nurse educators to boost prescriptions for its products.

**The case is part of a broader pack of lawsuits**, originally against 11 pharmaceutical companies — AbbVie, Amgen, AstraZeneca, Bayer, Biogen, Eli Lilly, EMD Serono, Gilead, Teva, Otsuka and UCB. Research company National Healthcare Analysis Group alleges they paid nurses to blur the line between a caregiver helping patients understand their medicines and a marketer pushing certain products. DOJ has tried to dismiss the suits, arguing that investigating the claims would be a huge financial burden and that the analysis group is just trying to make a profit off the drugmakers.

**The judge is unconvinced.** The federal government didn't fully investigate each claim and might be motivated by animosity towards the research company, Judge Staci Yandle from the US District Court for the Southern District of Illinois [wrote in an order](#) denying the dismissal. Plaintiffs quickly filed notices on the other cases but three — against Amgen, EMD Serono and Otsuka — have already been dismissed by other judges. The AbbVie and Gilead suits folded after whistleblowers withdrew.

## COMING UP IN PHARMA

**Tuesday-Wednesday:** The Forum on Neuroscience and Nervous System Disorders [hosts](#) a workshop on gene-targeted therapies for central nervous system disorders.

**Thursday:** FDA's Antimicrobial Drugs Advisory Committee [meets](#) to discuss potential antibodies for the rabies virus.



## PHARMA IN THE STATES

**TENNESSEE LAW LIMITS LAWYER ADS TARGETING DRUGS, DEVICES** — The state has become the first in the country to pass a law limiting ads from trial lawyers that target prescription drugs and medical devices. The law emerged due to concerns that the ads may scare consumers from taking their medicines. The new restrictions, which take effect in July, include a ban on ads that display the logo of a government agency or use the word "recall" if a product hasn't been recalled. Ads are also not allowed to be depicted as medical, health or consumer alerts, or as public service announcements.

The advertisements must disclose they are paid for by lawyers, and include a warning that consumers should not stop taking their prescribed medicine without consulting their doctor, due to the risk of injury or death. Unless the product has been recalled, the ads must make clear the product is still FDA approved.

**CALIFORNIA DRUG PURCHASING PLAN SHADED IN SECRECY** — Gov. Gavin Newsom announced his ambitious bulk drug purchasing plan on his first day in office — but 100 days later, few details have leaked out, leaving the health industry scrambling to prepare, Pro California's Angela Hart and Victoria Colliver report.

Newsom's plan calls for pooling the state's drug purchasing power to negotiate prices under a single system for 13.2 million Medicaid patients. A nonpartisan state office says the plan could save California "hundreds of millions of dollars annually" but that estimate is "highly uncertain" without important details. Newsom has given officials a July deadline to finalize the report.

**California's not alone:** Several states are exploring bulk plans, ranging from combining agency purchases to joining up with other states to boost leverage, writes Jane Horvath of the National Academy for State Health Policy. Read her rundown on state actions here.

## PHARMA IN EUROPE

**EU PARLIAMENT APPROVES CONTROVERSIAL GENERIC DRUG PLAN** — The European Parliament voted 572-63 Wednesday in favor of a plan to let companies manufacture generic drugs in Europe while they are still under patent protection in the bloc. The generic drugs could then be exported to countries outside the EU, our European colleague Katie Jennings writes. Manufacturers could also stockpile generics for sale in the EU six months ahead of when the product loses EU patent extension protections. The proposal, opposed by the brand drug industry, still needs to be approved by the Council of the EU. This final step is largely a formality and expected to occur by June at the latest.

**BEN WHITE AND MORNING MONEY HEAD TO #MIGLOBAL:** POLITICO is partnering with the Milken Institute for this year's global conference in Beverly Hills, Calif., from April 28 to May 1. Ben White will once again write a special Morning Money newsletter for the conference, detailing all the happenings, highlights, major conversations, evening festivities and buzzy VIP gatherings. [Sign up today](#) to receive exclusive coverage and everything you need to know direct from #MIGlobal in this special-edition, pop-up newsletter.

## QUICK HITS

**CRISPR human trial begins in U.S.** — The first U.S. CRISPR clinical trial began at the University of Pennsylvania in Philadelphia, in collaboration with the Parker Institute for Cancer Immunotherapy and Tmunity Therapeutics Inc., [NPR reports](#). The [Phase 1 clinical trial](#) is testing the gene-editing technology as a way to help fight cancers like myeloma, melanoma and sarcoma. The news comes after the November 2018 scandal over a Chinese researcher who claimed he edited the hereditary genes of two embryos with CRISPR technology.

**Pharma ad spending hits \$6.5 billion** — Big Pharmaceutical companies spent almost \$6.5 billion on advertisements this year, according to a [Fierce Pharma analysis](#) of Kantar Media data. AbbVie's arthritis drug Humira topped the list, with \$487 million in advertisement spending. Pfizer drugs took the next three slots: Lyrica, Xeljanz and Chantix. But the report notes that next year's assessment may look different, since Pfizer has decreased ad spending for the Lyrica, which faces increased competition after losing patent protection.

## PHARMA MOVES

**Doug Andres** is moving over to Sen. [Mitch McConnell](#)'s office to work as press secretary after a brief stint at the FDA, [POLITICO Playbook reports](#). Andres previously worked for former House Speaker Paul Ryan.

**Jun e Wasser** , executive director of FDA's Reagan-Udall Foundation, is leaving in early May, the organization [announced](#). **Amar Bhat**, who has held multiple executive positions with the foundation, will take over as interim executive director.

## DOCUMENT DRAWER

The Patient-Centered Outcomes Research Institute's Board of Governors [approved](#) almost \$45 million in funds for research on opioid use disorders, cancer pain and enhancing prenatal care.

FDA issued draft guidance outlining considerations for the use of metal alloy nitinol in medical devices.

## CATCHING OUR ATTENTION

**23andMe misses vast majority of breast cancer risks, says new study** — The popular consumer DNA testing company has told thousands of women whether they carry a BRCA gene mutation that puts them at risk for breast cancer — but nearly 90 percent of mutations may have been missed, according to an analysis presented at a genomics conference this week. That's because the company's testing formula relies on genetic variants most often found in Ashkenazi Jews, even though other mutations of the BRCA gene may be much more common, writes The New York Times' Heather Murphy. 23andMe isn't doing anything "actively deceptive" says a BRCA researcher — but the study makes the limitations of mail-in genetic testing clear. Read more [here](#).

[View online](#)

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POLITICOPRO

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This email was sent to [sarah.arbes@hhs.gov](mailto:sarah.arbes@hhs.gov) by: POLITICO, LLC 1000 Wilson Blvd. Arlington, VA, 22209, USA

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**From:** Ahsan, Sidra (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E35C4D5FD1054799828811EBE4187A59-AHSANS]  
**Sent:** 7/9/2019 9:19:00 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: NIH's Response to KEI's Comments Regarding Exclusive License in STAT3 Inhibitor, GLG-302

Thanks!

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Tuesday, July 9, 2019 5:02 PM  
**To:** Ahsan, Sidra (NIH/NCI) [E] <sidra.ahsan@nih.gov>  
**Subject:** RE: NIH's Response to KEI's Comments Regarding Exclusive License in STAT3 Inhibitor, GLG-302

b5

**From:** Ahsan, Sidra (NIH/NCI) [E] <sidra.ahsan@nih.gov>  
**Sent:** Tuesday, July 9, 2019 4:30 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** FW: NIH's Response to KEI's Comments Regarding Exclusive License in STAT3 Inhibitor, GLG-302

Hi Mark

Please see email below. Richard asked me to consult with you regarding this.

b5

b5

Best  
Sidra

**From:** kathryn ardizzone <kathryn.ardizzone@keionline.org>  
**Sent:** Tuesday, July 9, 2019 3:05 PM  
**To:** Ahsan, Sidra (NIH/NCI) [E] <sidra.ahsan@nih.gov>  
**Cc:** James Love <james.love@keionline.org>  
**Subject:** NIH's Response to KEI's Comments Regarding Exclusive License in STAT3 Inhibitor, GLG-302

Dear Dr. Ahsan:

On June 19, 2019, you emailed James Love, Director of Knowledge Ecology International (KEI), in response to our comments regarding the "Prospective Grant of an Exclusive Patent License: The Development and Use of a Therapeutic STAT3 Inhibitor, GLG-302, in All Proliferative Diseases, Where STAT3 Is Present, to GLG Pharma LLC located in Jupiter, Florida, USA."

A document attached to the email stated, in pertinent part: "We consider all comments prior to negotiating the proposed license. We will give your comments and suggestions serious consideration."

At 2:27 p.m. the same day, Mr. Love replied to your email and asked whether KEI will hear from NIH if it decides to proceed on the proposed license or accept or reject our suggestions. He also asked about the procedures for appealing under 37 C.F.R. § 404.11. You did not respond, and the link to the appeals procedure on NIH's website continues to be broken.

As soon as practicable, please clarify the following:

1. Does the document attached to your June 19, 2019 email constitute NIH's final decision regarding KEI's comments on the GLG-302 Stat 3 Inhibitor?; and
2. What are NIH's current appeal procedures and where they are disclosed to the public?

Thank you in advance for your consideration.

Sincerely,

--

Kathryn Ardizzone, Esq.  
Knowledge Economy International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009  
[kathryn.ardizzone@keionline.org](mailto:kathryn.ardizzone@keionline.org)  
(202) 332-2670



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**From:** Kassilke, Deborah (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/CN=OD/CN=KASSILKE]  
**Sent:** 1/12/2017 8:01:55 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/cn=OD/cn=ROHRBAUM]  
**Subject:** RE: For Mark

Conference call line: **b6**  
Passcode: **b6**

I'll dial in 5 mins early as the leader and activate it. You said 4PM today, yes?

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Thursday, January 12, 2017 2:57 PM  
**To:** Kassilke, Deborah (NIH/OD) [E] <deborah.kassilke@nih.gov>  
**Subject:** Re: For Mark

Sure

Sent from my iPhone

On Jan 12, 2017, at 2:56 PM, Kassilke, Deborah (NIH/OD) [E] <deborah.kassilke@nih.gov> wrote:

Yes, I would love to if you don't mind.  
Do you want to use my con call line info? **b5** if you need it.

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Thursday, January 12, 2017 2:53 PM  
**To:** Kassilke, Deborah (NIH/OD) [E] <deborah.kassilke@nih.gov>  
**Subject:** Re: For Mark

**b6** I scheduled it for 4 today. **b5**

Sent from my iPhone

On Jan 12, 2017, at 2:51 PM, Kassilke, Deborah (NIH/OD) [E] <deborah.kassilke@nih.gov> wrote:

**b5, b6**

Deb

---

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Thursday, January 12, 2017 12:35 PM  
**To:** Jamie Love <james.love@keionline.org>  
**Cc:** Claire Cassedy <claire.cassedy@keionline.org>  
**Subject:** RE: For Mark

REL0000023956

Jamie:

I can talk to her and am available today after 3:30 or tomorrow 10-11 or 2-4

Mark

**From:** jamespackardlove@gmail.com [mailto:jamespackardlove@gmail.com] **On Behalf Of** Jamie Love  
**Sent:** Wednesday, January 11, 2017 2:08 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>  
**Cc:** Claire Cassedy <claire.cassedy@keionline.org>  
**Subject:** For Mark

Mark, is there someone at the NIH that Claire can talk to about the policy on publishing notices about CRADAs?

We were surprised at few notices we found in the Federal Register.

Jamie

--

James Love. Knowledge Ecology International  
<http://www.keionline.org/donate.html>  
KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile:  
+41.76.413.6584, [twitter.com/jamie\\_love](https://twitter.com/jamie_love)

---

**From:** Rodriguez, Richard (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8092CB5394E04733AC0D4D84D25F65E5-RODRIGR]  
**Sent:** 11/7/2017 8:39:47 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW: responses to FRNs  
**Attachments:** KEI Comments July 22 2017 .pdf; Response to KEI Comments July 31 2017.pdf

Here is one recent example that you worked on with Surekha. I have some others but didn't want to spam you unless you wanted to see them.

---

**From:** Vathyam, Surekha (NIH/NCI) [E]  
**Sent:** Tuesday, November 7, 2017 1:40 PM  
**To:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
**Subject:** RE: responses to FRNs

Hi Richard,

I am attaching the KEI comment letter and our response which was formulated in consultation with Mark. This might be what Mark is referring to: b5

**b5**

Surekha

**SUREKHA VATHYAM, Ph.D.**  
Senior Technology Transfer Manager,  
National Cancer Institute Technology Transfer Center  
Main: 240-276-5530  
Direct: 240-276-6865  
Email: [vathyams@mail.nih.gov](mailto:vathyams@mail.nih.gov)

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**From:** Rodriguez, Richard (NIH/NCI) [E]  
**Sent:** Tuesday, November 7, 2017 12:45 PM  
**To:** NCI TTC Staff <[ncitdcbstaff-l@mail.nih.gov](mailto:ncitdcbstaff-l@mail.nih.gov)>  
**Subject:** FW: responses to FRNs

Please let me know if you have received such inquiries. I'd like to know which notice triggered the comments and a copy of the comments if you have them. If it was a call, a short email is fine.

Thanks,

Richard

---

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Tuesday, November 7, 2017 10:39 AM  
**To:** Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>  
**Subject:** responses to FRNs

Richard:

Do you recall our receiving questions from a FRN notice not directly related to the technology and the license, such as how much money was spent in developing this technology, or did this company receive government funding?

How was this handled or how are you handling it now?

Thx

Mark L. Rohrbaugh, Ph.D., J.D.  
Special Advisor for Technology Transfer  
Director, Division of Technology Transfer and Innovation Policy  
Office of Science Policy  
Office of the Director  
National Institutes of Health

---

**From:** Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=HAMMERSLAA]  
**Sent:** 5/1/2017 2:17:18 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]  
**Subject:** Dft Xtandi Response  
**Attachments:** Response 04292017 KEI 04282017 request.docx

Mark: Attached is OER's draft Xtandi Response. Let me know if you have any edits. Ann

--

Ann M. Hammersla, J.D.  
Director  
Division of Extramural Inventions and Technology Resources  
Office of Policy for Extramural Research Administration  
Rockledge 1, Suite 310  
6705 Rockledge Drive  
Bethesda, Maryland 20892-7974  
PHONE: 301-435-0745

**b5**

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**From:** Soukas, Peter (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B1F6020157AC47948C6E34166B78E433-SOUKASP]  
**Sent:** 1/30/2019 9:40:36 PM  
**To:** Berkley, Dale (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee461c29f5045a49f0adf82caaa2f31-berkleyd]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Puglielli, Maryann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f53ceacaf754875a948081bac5cc66a-pugliellim]; Williams, Richard (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5f89fe4d27a43abb936bb20efeca3b9-rwilliams]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]; Frisbie, Suzanne (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c402740ceaad4d4f97a8c28f16fbb349-frisbies]  
**Subject:** Zika KEI Response for Review Prospective licenses (Zika, not RSV), Federal Register notice 83 FR 65696  
**Attachments:** Response to KEI J Love Comments Zika 01 25 2019 .docx; FW: Prospective Grant of Exclusive License: Production of Monovalent Live Attenuated Zika Vaccines and Multivalent Live Attenuated Flavivirus Vaccines

Dear Dale and Mark,

As discussed last week, attached please find a draft response for your review to KEI's queries to us (in the email below) regarding Zika licensing.

We also attach KEI's email to us of June 7, which we reference in our letter.

As we noted during the call, we received a license application from Merck before the deadline. I am still formulating a licensing strategy. b5

Please contact us if you have any additional questions. Thank you.

Peter Soukas  
Phone: 301-594-8730  
Email: [ps193c@nih.gov](mailto:ps193c@nih.gov)

**From:** Luis Gil Abinader <[luis.gil.abinader@keionline.org](mailto:luis.gil.abinader@keionline.org)>  
**Sent:** Friday, January 11, 2019 2:22 PM  
**To:** Soukas, Peter (NIH/NIAID) [E] <[peter.soukas@nih.gov](mailto:peter.soukas@nih.gov)>  
**Cc:** Jamie Love <[james.love@keionline.org](mailto:james.love@keionline.org)>  
**Subject:** Prospective licenses, Federal Register notice 83 FR 65696

Dear Peter Soukas,

According to the Federal Register notice 83 FR 65696, the NIH intends to grant co-exclusive licenses over Zika and Dengue vaccines inventions to Medigen and Panacea, in a territory that "may be limited to India".

Why are these proposed co-exclusive licenses limited to India? Why does the NIH intends to grant these co-exclusive licenses to two companies, one in India and the other in Taiwan?

What is the state of development of these vaccines?

Is this the PCT patent application described in the notice?  
<https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2017156511>

Please provide copies of all the unpublished patent applications covered in these proposed co-exclusive licenses, including U.S. Provisional Patent Application Number 62/307,170 and Indian Patent Application Number 201817036778.

Thank you,

Luis Gil Abinader



**b5**

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**From:** Soukas, Peter (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B1F6020157AC47948C6E34166B78E433-SOUKASP]  
**Sent:** 6/7/2018 4:31:31 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Mowatt, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ef7e2e54b4164ae34814574bda638-mmowatt]  
**CC:** Frisbie, Suzanne (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c402740ceaad4d4f97a8c28f16fbb349-frisbies]; Puglielli, Maryann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f53ceacaf754875a948081bac5cc66a-pugliellim]; Williams, Richard (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5f89fe4d27a43abb936bb20efeca3b9-rwilliams]  
**Subject:** FW: Prospective Grant of Exclusive License: Production of Monovalent Live Attenuated Zika Vaccines and Multivalent Live Attenuated Flavivirus Vaccines

**Flag:** Follow up

Dear Mark and Mike,

I just received this email from KEI.

b5

b5

b5

Thanks.

Peter Soukas  
National Institutes of Health  
National Institute of Allergy and Infectious Diseases  
Phone: 301-594-8730  
Email: [ps193c@nih.gov](mailto:ps193c@nih.gov)

**From:** James Love <james.love@keionline.org>  
**Sent:** Thursday, June 7, 2018 12:16 PM  
**To:** Soukas, Peter (NIH/NIAID) [E] <peter.soukas@nih.gov>  
**Cc:** Manon Ress <manon.ress@keionline.org>; luis.gil.abinader@keionline.org; Claire Cassedy <claire.cassedy@keionline.org>  
**Subject:** Prospective Grant of Exclusive License: Production of Monovalent Live Attenuated Zika Vaccines and Multivalent Live Attenuated Flavivirus Vaccines

Peter Soukas, Technology Transfer and Patent Specialist,  
Technology Transfer and Intellectual Property Office,  
National Institute of Allergy and Infectious Diseases,  
National Institutes of Health,  
Email:

[ps193c@nih.gov](mailto:ps193c@nih.gov)

Dear Peter Soukas,

We are responding to the request for comments on the Prospective Grant of Exclusive License: Production of Monovalent Live Attenuated Zika Vaccines and Multivalent Live Attenuated Flavivirus Vaccines, to Medigen Vaccines Biologics Corp. (Medigen), having a place of business in Zhubei, Taiwan.

\*

We note the "  
The Licensed Territory may be limited to Europe, China, South Korea, Japan, India, Australia and New Zealand.

REL0000023962.0002

"

We oppose granting an exclusive license in the Territory of India, a country with an average income of \$1,670 in 2016, according to the World Bank. India is also a possible source of the vaccine for other developing countries, so the granting of an exclusive license may result in broader restrictions on access.

Sincerely,

James Love  
KEI

\*

<https://www.federalregister.gov/documents/2018/05/25/2018-11258/prospective-grant-of-exclusive-license-production-of-monovalent-live-attenuated-zika-vaccines-and>

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**From:** Joe Allen [jallen@allen-assoc.com]  
**Sent:** 4/20/2019 1:04:31 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Hammersla, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87fb28aa23744c0b855ef0683ac2e8b4-hammerslaa]  
**Subject:** Politico: Commerce expected to slash march in rights for drugs

<https://www.politico.com/newsletters/prescription-pulse/2019/04/19/commerce-department-expected-to-slash-march-in-rights-for-drugs-426742>

**COMMERCE REPORT: MARCH-IN RIGHTS SHOULDN'T BE USED AS DRUG PRICE CONTROL TOOL** — Advocates of lower drug costs are concerned that the Department of Commerce's National Institute of Standards and Technology will finalize a little-noticed [green paper](#) that recommends against the government exercising its "march-in" rights to help lower the cost of medicines. NIST said the final paper should be released next week. It will be reviewed by an interagency panel, and regulatory changes could follow. Many Democrats in Congress have raised the possibility of using march-in rights or similar authority to revoke patent rights or marketing exclusivity on certain drugs. They've tried to use the idea as a stick to encourage companies to cooperate on drug price negotiations.

**The background:** The 1980 Bayh-Dole Act laid out a pathway to freely transfer inventions and patent rights resulting from federally funded research to non-government organizations, so they could be commercialized. But the law outlined limited circumstances where the government could "march in" and let other parties produce the patented invention, including when health and safety needs were not being satisfied in a reasonable way. Groups like Doctors Without Borders and Knowledge Ecology International have petitioned NIH to claim that the high cost of a medication can satisfy the definition of an unmet need. So far, NIH has never agreed with this argument.

Now, NIST is recommending changes to Bayh-Dole Act regulations to ensure march-in rights are never used to control the price of a good, specifically pharmaceuticals.

**Advocates push back:** Doctors Without Borders has strongly objected to the idea. "Agencies relying on public funds to develop life-saving medicines should not seek to curtail the public's right to appropriate, affordable access to products developed with public support by this proposed unilateral regulatory action," the group wrote in [comments on the green paper](#). The change it proposes "goes against the stated goals of the administration to lower drug prices and calls by more than 50 members of Congress to use march-in rights to address 'soaring' pharmaceutical prices." The group notes that a [March 2018 study](#) found NIH funding contributed to each of the 210 new drugs approved by FDA from 2010 through 2016.

Eleven groups including Doctors Without Borders, Public Citizen, Social Security Works and the Yale Global Health Justice Partnership [wrote Congress](#) earlier this month urging lawmakers to oppose the change. They also raised concerns that another suggestion in the report could harm access to affordable medicines. This change would narrow the government's royalty-free rights to inventions whose development it funded, to exclude situations where the government isn't directly using or consuming the patented good. This would prevent the government from using royalty-free rights to provide affordable drugs in Medicare or other government programs.

"At a time when drug prices have become increasingly unaffordable for American patients, the administration's proposals in the NIST paper outline provisions designed to protect pharmaceutical companies that sell expensive treatments, and exempt them from obligations to ensure that treatments are affordable and accessible," the letter says.

--

Joseph P. Allen  
President  
Allen and Associates  
60704 Rt. 26, South  
Bethesda, OH 43719  
(W) 740-484-1814  
(c) b6  
www.allen-assoc.com

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**From:** Shmilovich, Michael (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DFE19BFD1D443CEB700B9F22D159A90-SHMILOVM]  
**Sent:** 7/25/2019 4:10:37 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: TDTC FYI - "KEI Letter to US House Oversight Committee on NIH Misconduct and Lack of Transparency"

b5

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Thursday, July 25, 2019 12:10  
**To:** Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>  
**Subject:** RE: TDTC FYI - "KEI Letter to US House Oversight Committee on NIH Misconduct and Lack of Transparency"

If congress asks us

**From:** Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>  
**Sent:** Thursday, July 25, 2019 12:09 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** FW: TDTC FYI - "KEI Letter to US House Oversight Committee on NIH Misconduct and Lack of Transparency"

Is NIH planning on responding?

**From:** Mowatt, Michael (NIH/NIAID) [E]  
**Sent:** Wednesday, July 24, 2019 15:09  
**To:** NIH TDC Long <niaaattcdcl-l@mail.nih.gov>  
**Subject:** TDTC FYI - "KEI Letter to US House Oversight Committee on NIH Misconduct and Lack of Transparency"

<https://www.keionline.org/31247>

**Michael R. Mowatt, Ph.D.**  
Director, Technology Transfer and Intellectual Property Office

**National Institute of Allergy and Infectious Diseases**  
National Institutes of Health  
U.S. Department of Health and Human Services

+1 301 496 2644



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REL0000023968



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**From:** Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]  
**Sent:** 6/13/2018 4:47:34 PM  
**To:** Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodgr]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** FW: BEORO Therapeutics license

Please see below for Mr. Love's response. Let me know whether I should respond further.

David A. Lambertson, Ph.D.  
Senior Technology Transfer Manager  
Technology Transfer Center  
National Cancer Institute/NIH  
[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)  
<http://ttc.nci.nih.gov/>

9609 Medical Center Drive, Rm 1-E530 MSC 9702  
Bethesda, MD 20892-9702 (USPS)  
Rockville, MD 20850-9702 (Overnight/express mail)  
Phone (Main Office): 240-276-5530  
Phone (direct): (240) 276-6467  
Fax: 240-276-5504

**Note: This email may contain confidential information. If you are not the intended recipient, any disclosure, copying or use of this email or the information enclosed therein is strictly prohibited, and you should notify the sender for return of any attached documents**

**From:** James Love [mailto:james.love@keionline.org]  
**Sent:** Wednesday, June 13, 2018 12:40 PM  
**To:** Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>  
**Subject:** Re: BEORO Therapeutics license

David, thank you for your email. Wholly apart from our lawsuit on a completely different license, why is it business confidential information "if there any former NIH employees involved with the company", if the company "has a track record of developing new drugs or treatments" or "if the company will manufacture or conduct research in the United States"?

And, if the public can't get answers to questions like these, how is the public's right to comment on proposed exclusive licenses enabled?

Jamie

1. What is the proposed consideration for the exclusive license?
2. Are there any former NIH employees involved with the company?
3. Does this company have a track record of developing new drugs or treatments?
4. Will the company manufacture or conduct research in the United States.
5. Did the NIH do any analysis to see if a term that is less than the life of a patent would be appropriate and sufficient?
6. Did the NIH ask DOJ for a review, under 40 USC 559?

----- Forwarded message -----

**From:** Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>  
**Date:** Wed, Jun 13, 2018 at 11:09 AM

REL0000023970

Subject: RE: BEORO Therapeutics license  
To: James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>

Mr. Love,

Thank you for your e-mail. The questions that you pose relate either to business confidential information for the applicant or an ongoing lawsuit you have filed, and we cannot discuss these as a result.

Regards,

David A. Lambertson, Ph.D.

Senior Technology Transfer Manager

Technology Transfer Center  
National Cancer Institute/NIH  
[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)

<http://ttc.nci.nih.gov/>

9609 Medical Center Drive, Rm 1-E530 MSC 9702

Bethesda, MD 20892-9702 (USPS)

Rockville, MD 20850-9702 (Overnight/express mail)

Phone (Main Office): 240-276-5530

Phone (direct): (240) 276-6467

Fax: 240-276-5504

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**From:** James Love [<mailto:james.love@keionline.org>]

**Sent:** Thursday, June 07, 2018 5:00 AM

REL0000023970



**To:** Lambertson, David (NIH/NCI) [E] <[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)>

**Subject:** BEORO Therapeutics license

David A. Lambertson, Ph.D.,  
Senior Technology Transfer Manager,  
NCI Technology Transfer Center  
Email:

[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov).

David, we intend to file comments on this license. Below is a draft of what we will file, probably with other groups. We would like to call to explain the motivation for these various requests, including the transparency proposals.

Also, can you answer a few questions about the license.

1. What is the proposed consideration for the exclusive license?
2. Are there any former NIH employees involved with the company?
3. Does this company have a track record of developing new drugs or treatments?
4. Will the company manufacture or conduct research in the United States.
5. Did the NIH do any analysis to see if a term that is less than the life of a patent would be appropriate and sufficient?
6. Did the NIH ask DOJ for a review, under 40 USC 559?

Jamie

Knowledge Ecology International (KEI), , and \_\_\_\_\_ are organizations concerned about drug pricing and access to

REL0000023970

patented medicines, offering comments on the grant of an exclusive license, between the National Institutes of Health (NIH) and

BEORO Therapeutics, GmbH. ("Beoro") located in Seefeld, Germany, for patents noticed in the Federal Register (83 FR 26487) the Development of an Anti-BCMA Immunotoxin for the Treatment of Human Cancer.

(See: <https://www.gpo.gov/fdsys/pkg/FR-2018-06-07/pdf/2018-12179.pdf>)

The above entities oppose the issuing of the license unless:

A. The NIH has determined that an exclusive license is "a reasonable and necessary incentive" to induce investments for the development and practical application of the invention, as is required by 35 USC § 209, and shares its analysis with the public; and

B. The NIH limits the scope of rights for the exclusivity to only those rights reasonably necessary to induce investments for the development and practical application of the invention, and in particular, that the field of use is sufficiently narrow, that the term of the exclusivity is sufficiently limited, and that the license contains sufficient safeguards to ensure that the invention is "available to the public on reasonable terms," as is required by 35 USC § 209 and 35 USC § 201(f).

Our comments address three areas of concern, (1) the pricing, affordability and access issues, (2) freedom for researchers to use the inventions, and (3) requirements for transparency of the development and commercialization of the medicine.

We propose the following safeguards regarding the pricing of and access to products that use the inventions:

1.

Products are priced no higher in the United States than the median price charged in the seven largest economies as measured by nominal GNI that have a nominal GNI per capita of at least 50 percent of the United States. To fully appreciate our concerns about the discriminatory pricing that makes US residents pay more than everyone else, please review the cross country price comparisons here: <http://drugdatabase.info/drug-prices/>

2.

Prices for products in the United States do not exceed the estimated value of the treatment, as determined by independent health technology assessments selected by Department of Health and Human Services (HHS).

3.

Patient co-payments under third party Medicare and private reimbursement programs are affordable.

4.

The geographic area for the exclusivity should exclude countries with a per capita income less than 30 percent that of the United States. If there is no such exclusion, the company be required to report annually on the reasonable and feasible measures that will be taken to ensure access to patients living in such countries. Here, please note the data from <http://drugdatabase.info/drug-prices/>, which shows that in many developing countries, prices are frequently higher than the prices for high income countries in Europe, despite the much lower per capita income in developing

countries (including for taxpayer funded cancer drugs), illustrating the need for a policy to be included in NIH licenses. We also note the Medicines Patent Pool (MPP) has recently announced it will expand the scope of diseases for its licenses. The NIH should retain the flexibility to provide licenses to the MPP in the future, perhaps as an option clause in the license.

5.

The initial period of exclusivity is set at seven years, subject to extensions if the company can demonstrate it has not recovered sufficient profits given the risk-adjusted value of the clinical trials used to register similar drugs for the lead indication.

6.

Absent satisfaction of the requirements of proposed safeguard number 5, the exclusivity of the product be reduced when cumulative global revenues for the product exceed \$1 billion, by one year for every \$0.5 billion in cumulative sales that exceed \$1 billion in cumulative sales.

The NIH might consider a different set of benchmarks than \$1 billion and \$.5 billion. In considering any benchmarks for global sales benchmarks, n

ote that the licensing of inventions to the company significantly reduces the company's costs of preclinical research, which various studies have estimated to be 40 to 55 percent of drug development costs on a risk- and capital cost-adjusted basis.

To address research by third parties on the patented invention, we propose the NIH explicitly permit researchers worldwide to use the inventions for research purposes, regardless of whether or not research has a grant or contract from a U.S. government agency, and for both profit or non-profit organizations.

To address transparency, we proposes the company be required to provide an annual report for the public providing disclosures of the following items:

1.

The amount of money R&D to obtain FDA and foreign government approvals of the inventions, including in particular, the amount of money spent each year on each trial, and the relevant tax credits, grants and other subsidies received from any government or charity relating to those R&D outlays,

2.

The prices and revenue for the products, by country,

3.

The number of units sold, in each country,

4.

The product-relevant patents obtained in each country, and

5.

The regulatory approval obtained in each country.

--

James Love. Knowledge Ecology International

<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, [twitter.com/jamie\\_love](https://twitter.com/jamie_love)

--

James Love. Knowledge Ecology International

<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, [twitter.com/jamie\\_love](https://twitter.com/jamie_love)

---

**From:** Freel, Rose (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E8AE9AAB7E3249E881BB573E9A189036-FREELRM]  
**Sent:** 6/29/2018 8:42:33 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: 83 FR 30448, Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

Sure that works fine. I can be reached at 301-624-1257. Thanks!

Rose

Sent with BlackBerry Work  
(www.blackberry.com)

---

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Date:** Friday, Jun 29, 2018, 4:15 PM  
**To:** Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov>  
**Subject:** RE: 83 FR 30448, Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

Ok. How about 2 pm?

**From:** Freel, Rose (NIH/NCI) [E]  
**Sent:** Friday, June 29, 2018 4:01 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>  
**Subject:** RE: 83 FR 30448, Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

Hi Mark,

Sorry, just seeing this now. Would Monday work? My schedule is very flexible then.

Thanks!

Rose

---

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Date:** Friday, Jun 29, 2018, 1:12 PM  
**To:** Freel, Rose (NIH/NCI) [E] <rose.freel@nih.gov>  
**Subject:** RE: 83 FR 30448, Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

Rose:

Do you have a few minutes this afternoon to talk?

Thanks,  
Mark

REL0000023971

**From:** Freel, Rose (NIH/NCI) [E]  
**Sent:** Friday, June 29, 2018 9:26 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <[RohrBauM@OD.NIH.GOV](mailto:RohrBauM@OD.NIH.GOV)>  
**Cc:** Rodriguez, Richard (NIH/NCI) [E] <[richard.rodriguez@nih.gov](mailto:richard.rodriguez@nih.gov)>  
**Subject:** FW: 83 FR 30448, Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

Hi Mark,

See email below from KEI regarding a FR Notice for intent to grant. Let me know when you have time to discuss.

Thanks!

Rose

--

Rose Santangelo Freel, Ph.D.  
Technology Transfer Manager  
**National Cancer Institute**  
P 301-624-1257 | [rose.freel@nih.gov](mailto:rose.freel@nih.gov)

**From:** James Love [<mailto:james.love@keionline.org>]  
**Sent:** Thursday, June 28, 2018 4:04 PM  
**To:** Freel, Rose (NIH/NCI) [E] <[rose.freel@nih.gov](mailto:rose.freel@nih.gov)>  
**Cc:** Claire Cassedy <[claire.cassedy@keionline.org](mailto:claire.cassedy@keionline.org)>  
**Subject:** 83 FR 30448, Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

Rose M. Freel, Ph.D.,  
Licensing and Patenting Manager,  
NCI Technology Transfer Center,  
8490 Progress Drive, Suite 400, Frederick, MD 21701;  
Email: [rose.freel@nih.gov](mailto:rose.freel@nih.gov).

Dear Dr  
Freel,

Has the technology referred to in 83 FR 30448, regarding Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer, been subject to any clinical trials (1) funded by the NIH, or (2) funded by any other party?

This information is useful for KEI in preparing our comments on the license.

Jamie

--

James Love. Knowledge Ecology International  
<http://www.keionline.org/donate.html>  
KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, [twitter.com/jamie\\_love](https://twitter.com/jamie_love)

REL0000023971

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**From:** Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]  
**Sent:** 9/1/2017 3:02:17 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Rodriguez, Richard (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8092cb5394e04733ac0d4d84d25f65e5-rodgrig]; Rucker, Susan (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31fefefc79364fdaaf8dca7a10dea9ab-ruckersu]  
**Subject:** Re: KEI Request FOIA Request Re: CRADAs Executed 2010-2017

I don't handle any Kite CRADAs. Please contact either Andy Burke/Aida Cremesti or Manna Berhane if you need input regarding a CRADA.

Sent with BlackBerry Work (www.blackberry.com)

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**From:** "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>  
**Sent:** Sep 1, 2017 10:35 AM  
**To:** "Rodriguez, Richard (NIH/NCI) [E]" <richard.rodriguez@nih.gov>; "Lambertson, David (NIH/NCI) [E]" <david.lambertson@nih.gov>; "Rucker, Susan (NIH/NCI) [E]" <susan.rucker@nih.gov>  
**Subject:** FW: KEI Request FOIA Request Re: CRADAs Executed 2010-2017

FYI See proposed response to KEI from FOIA

b5

**From:** Rogers, Karen (NIH/OD) [E]  
**Sent:** Friday, September 01, 2017 10:18 AM  
**To:** NIH FOIA <nihfoia@od.nih.gov>  
**Cc:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>; Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov>; Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>; Deutch, Alan (NIH/NHLBI) [E] <deutch@nhlbi.nih.gov>; Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>  
**Subject:** Re: KEI Request FOIA Request Re: CRADAs Executed 2010-2017

Morning Roger - I'm fine with the response. Regards, Karen

Sent from my iPhone

*Karen L. Rogers  
Acting Director,  
Senior Royalties Administrator*

*Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard, Suite 325  
Rockville, MD 20852  
E-Mail: [RogersK@nih.gov](mailto:RogersK@nih.gov)  
Phone: [301-435-4359](tel:301-435-4359)  
Fax: [301-402-8678](tel:301-402-8678)*

**SENSITIVE/CONFIDENTIAL INFORMATION**

REL0000023972



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On Sep 1, 2017, at 10:09 AM, NIH FOIA <nihfoia@od.nih.gov> wrote:

Good Morning Everyone,

I still have not received approval from everyone on sending this reply back to KEI.

Can everyone please let me know today if you think this is okay to send to them?

Thank you.

**Roger Bordine**

Program Assistant  
Freedom of Information Office  
National Institutes of Health  
Building 31, Room 5B35  
31 Center Drive  
Bethesda, MD 20892

Phone: 301-496-5633

Fax: 301-402-4541

[Roger.bordine@nih.gov](mailto:Roger.bordine@nih.gov)

<image001.png>

**From:** NIH FOIA

**Sent:** Monday, August 28, 2017 4:24 PM

**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Shmilovich, Michael (NIH/NHLBI) [E] <[michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov)>; Bordine, Roger (NIH/OD) [E] <[roger.bordine@nih.gov](mailto:roger.bordine@nih.gov)>; Deutch, Alan (NIH/NHLBI) [E] <[deutch@nhlbi.nih.gov](mailto:deutch@nhlbi.nih.gov)>

**Cc:** Thomas, Gina (NIH/OD) [E] <[gthomas@od.nih.gov](mailto:gthomas@od.nih.gov)>; Rogers, Karen (NIH/OD) [E] <[rogersk@od.nih.gov](mailto:rogersk@od.nih.gov)>; Burklow, John (NIH/OD) [E] <[burklowj@od.nih.gov](mailto:burklowj@od.nih.gov)>; NIH FOIA <[nihfoia@od.nih.gov](mailto:nihfoia@od.nih.gov)>

**Subject:** RE: KEI Request FOIA Request Re: CRADAs Executed 2010-2017

Good afternoon everyone,

After our conference call today, we decided to draft a response to KEI's initial email regarding the status of their request, and to have as many people give input as possible before sending it out. If you have not already done so, please see the email from James Love at KEI below. KEI also sent a follow up email that I have attached requesting more specific/named records regarding the NIH CRADA with Kite Pharmaceuticals. We will also be responding to this follow-up email in the draft below.

DRAFT EMAIL TO KEI:

**b5**

REL0000023972



# b5

So please feel free to add or edit out anything in the draft email above. Hopefully we can all agree on a quick email back to KEI.

Thanks everyone.

**Roger Bordine**

Program Assistant  
Freedom of Information Office  
National Institutes of Health  
Building 31, Room 5B35  
31 Center Drive  
Bethesda, MD 20892

Phone: 301-496-5633

Fax: 301-402-4541

[Roger.bordine@nih.gov](mailto:Roger.bordine@nih.gov)

<image001.png>

**From:** Rohrbaugh, Mark (NIH/OD) [E]

**Sent:** Monday, August 28, 2017 3:10 PM

**To:** Shmilovich, Michael (NIH/NHLBI) [E] <[michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov)>; NIH FOIA <[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov)>; Bordine, Roger (NIH/OD) [E] <[roger.bordine@nih.gov](mailto:roger.bordine@nih.gov)>; Deutch, Alan (NIH/NHLBI) [E] <[deutcha@nhlbi.nih.gov](mailto:deutcha@nhlbi.nih.gov)>

**Cc:** Thomas, Gina (NIH/OD) [E] <[gthomas@od.nih.gov](mailto:gthomas@od.nih.gov)>; Rogers, Karen (NIH/OD) [E] <[rogersk@od.nih.gov](mailto:rogersk@od.nih.gov)>

**Subject:** RE: KEI Request FOIA Request Re: CRADAs Executed 2010-2017

Ok by me

**From:** Shmilovich, Michael (NIH/NHLBI) [E]

**Sent:** Monday, August 28, 2017 2:56 PM

REL0000023972

**To:** Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; NIH FOIA <[nihfoia@od.nih.gov](mailto:nihfoia@od.nih.gov)>; Bordine, Roger (NIH/OD) [E] <[roger.bordine@nih.gov](mailto:roger.bordine@nih.gov)>; Deutch, Alan (NIH/NHLBI) [E] <[deutcha@nhlbi.nih.gov](mailto:deutcha@nhlbi.nih.gov)>  
**Cc:** Thomas, Gina (NIH/OD) [E] <[gthomas@od.nih.gov](mailto:gthomas@od.nih.gov)>  
**Subject:** RE: KEI Request FOIA Request Re: CRADAs Executed 2010-2017

Ok I have a telecon at 15:05 can we gab at 15:30?

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Monday, August 28, 2017 14:56  
**To:** NIH FOIA <[nihfoia@od.nih.gov](mailto:nihfoia@od.nih.gov)>; Shmilovich, Michael (NIH/NHLBI) [E] <[michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov)>; Bordine, Roger (NIH/OD) [E] <[roger.bordine@nih.gov](mailto:roger.bordine@nih.gov)>; Deutch, Alan (NIH/NHLBI) [E] <[deutcha@nhlbi.nih.gov](mailto:deutcha@nhlbi.nih.gov)>  
**Cc:** Thomas, Gina (NIH/OD) [E] <[gthomas@od.nih.gov](mailto:gthomas@od.nih.gov)>  
**Subject:** RE: KEI Request FOIA Request Re: CRADAs Executed 2010-2017

I am available the rest of today and tomorrow until 1 pm.

Mark

**From:** NIH FOIA  
**Sent:** Monday, August 28, 2017 10:32 AM  
**To:** Shmilovich, Michael (NIH/NHLBI) [E] <[michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov)>; Bordine, Roger (NIH/OD) [E] <[roger.bordine@nih.gov](mailto:roger.bordine@nih.gov)>; Deutch, Alan (NIH/NHLBI) [E] <[deutcha@nhlbi.nih.gov](mailto:deutcha@nhlbi.nih.gov)>  
**Cc:** [Deborah.Kassilke@nih.gov](mailto:Deborah.Kassilke@nih.gov); Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>; Thomas, Gina (NIH/OD) [E] <[gthomas@od.nih.gov](mailto:gthomas@od.nih.gov)>  
**Subject:** RE: KEI Request FOIA Request Re: CRADAs Executed 2010-2017

Good Morning,

I have not yet responded, and I have cc'd Gina Thomas at OTT FOIA as well. She is handling two FOIA request cases from KEI about CRADA lists and tech transfer records.

Let me know when is best to talk with all of you so we can figure out the best way to respond soon.

Thanks.

**Roger Bordine**  
Program Assistant  
Freedom of Information Office  
National Institutes of Health  
Building 31, Room 5B35  
31 Center Drive  
Bethesda, MD 20892

Phone: 301-496-5633  
Fax: 301-402-4541  
[Roger.bordine@nih.gov](mailto:Roger.bordine@nih.gov)

<image001.png>

**From:** Shmilovich, Michael (NIH/NHLBI) [E]  
**Sent:** Monday, August 28, 2017 9:52 AM  
**To:** Bordine, Roger (NIH/OD) [E] <[roger.bordine@nih.gov](mailto:roger.bordine@nih.gov)>; Deutch, Alan (NIH/NHLBI) [E] <[deutch@nhlbi.nih.gov](mailto:deutch@nhlbi.nih.gov)>  
**Cc:** NIH FOIA <[niinfoia@od.nih.gov](mailto:niinfoia@od.nih.gov)>; [Deborah.Kassilke@nih.gov](mailto:Deborah.Kassilke@nih.gov); Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Subject:** RE: KEI Request FOIA Request Re: CRADAs Executed 2010-2017

Roger –

b5

b5

Can you, Mark and me have a conversation first before you respond if at all?

Thank you!!

**Michael A. Shmilovich, Esq., CLP**

<image002.jpg>

Office of Technology Transfer and Development  
31 Center Drive Room 4A29, MSC2479  
Bethesda, MD 20892-2479  
o. 301.435.5019  
[shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov)

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**From:** [jamespackardlove@gmail.com](mailto:jamespackardlove@gmail.com) [<mailto:jamespackardlove@gmail.com>] **On Behalf Of** Jamie Love  
**Sent:** Monday, August 28, 2017 08:28  
**To:** Bordine, Roger (NIH/OD) [E] <[roger.bordine@nih.gov](mailto:roger.bordine@nih.gov)>  
**Cc:** Claire Cassedy <[claire.cassedy@keionline.org](mailto:claire.cassedy@keionline.org)>; NIH FOIA <[niinfoia@od.nih.gov](mailto:niinfoia@od.nih.gov)>; [Deborah.Kassilke@nih.gov](mailto:Deborah.Kassilke@nih.gov); Shmilovich, Michael (NIH/NHLBI) [E] <[michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov)>; Rohrbaugh, Mark (NIH/OD) [E] <[rohrbaum@od.nih.gov](mailto:rohrbaum@od.nih.gov)>  
**Subject:** KEI Request FOIA Request Re: CRADAs Executed 2010-2017

Dear Roger Bordine,

I am attaching some correspondence I have had the NIH over the issue of CRADAs. When we respond to an NIH request for comments on an exclusive license, we often ask for the CRADA, if any, associated with the license. For example, recently we requested the CRADA associated with the miRecale CRADA, which involves a recent former NIH employee. Typically, as in the case of MiRecale, the NIH licensing officials refuses to give us a copy of the CRADA, claiming it is confidential. We both know that the CRADA document is in fact subject to FOIA, but FOIA takes a long time, can will not be processed before the comment period closes.

When we asked the Office of the Director for a list of all CRADA agreements earlier this year, we were told that the NIH would not provide such a list, because the information was in a computer database and the NIH was not required to create the list from the database under FOIA. We noted at the time that this would force us to FOIA all of the CRADAs, which we thought would be a waste of everyone's time, an opinion that you seemed to share.

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Why doesn't the NIH do what some other federal agencies do and list the CRADAs, all of them, on the NIH web page, to enhance the transparency of the licensing and technology transfer operations?

In any event, please decide if the NIH wants to provide a list of the CRADAs or not, and if we have to sue to get copies if you won't in fact provide such a list.

The NIH knows full well the Congress, the press, academic researchers, taxpayer and patient advocacy groups all want to have more transparency of NIH technology transfer activities. The continual stonewalling of legitimate requests for public documents is inappropriate for an agency like the NIH that manages billions of taxpayer dollars to address important health issues, and where the pricing of NIH funded products is a major concern.

In the meantime, please provide KEI with a copy of the miRecule CRADA, and the list of the CRADAs, asap.

James Love  
Knowledge Ecology International

Attached are portions of some previous correspondence with the NIH.

----- Forwarded message -----

From: **NIH FOIA** <[niinfoia@od.nih.gov](mailto:niinfoia@od.nih.gov)>

Date: Wed, Aug 16, 2017 at 5:15 PM

Subject: RE: Request FOIA Request Re: CRADAs Executed 2010-2017

To: Claire Cassedy <[claire.cassedy@keionline.org](mailto:claire.cassedy@keionline.org)>

Cc: NIH FOIA <[niinfoia@od.nih.gov](mailto:niinfoia@od.nih.gov)>

Good Afternoon,

Thank you for your NIH FOIA request.

Upon reading your request, it appears as though you are asking for all CRADAs from the NIH between 2010-2017, and as it stands, that aspect of your request is too broad and would involve searching records from all of the 27 institutes and centers at the NIH.

Searching for this many records, and the review efforts afterwards, would put an undue burden on Federal Government resources, as stipulated in the FOIA, and as such, requires you to narrow the scope of your request.

It is estimated that, within your requested timeframe, there would be hundreds of CRADAs across the NIH's institutes, and if you would like to submit a new/revised request detailing a smaller number of specifically named/individual CRADAs, you are more than welcome to request those records. If not, and you would rather request just a list of CRADAs and not the CRADA records themselves, you may do that instead.

Please let us know if you would like to withdraw this initial request in favor of submitting a new request for clarified/named records.

Thank you, and please let us know if you have any questions.

**Roger Bordine**  
Program Assistant  
Freedom of Information Office  
National Institutes of Health  
Building 31, Room 5B35  
31 Center Drive  
Bethesda, MD 20892

Phone: 301-496-5633  
Fax: 301-402-4541  
Roger.bordine@nih.gov

----- Forwarded message -----

From: **James Love** <[jamespackardlove@gmail.com](mailto:jamespackardlove@gmail.com)>  
Date: Thu, Jan 19, 2017 at 7:34 PM  
Subject: Re: Your requests for information from NIH OTT  
To: "Rohrbaugh, Mark (NIH/OD) [E]" <[RohrBauM@od.nih.gov](mailto:RohrBauM@od.nih.gov)>  
Cc: "Kassilke, Deborah (NIH/OD) [E]" <[deborah.kassilke@nih.gov](mailto:deborah.kassilke@nih.gov)>, "[claire.cassedy@keionline.org](mailto:claire.cassedy@keionline.org)" <[claire.cassedy@keionline.org](mailto:claire.cassedy@keionline.org)>

We can't FOIA a database or require records be generated under FOIA. We can FOIA every CRADA, which is what we are going to be forced to do.

But if we knew what records were in the database, a query might save everyone a lot of time.

On Fri, Jan 20, 2017 at 1:07 AM, Rohrbaugh, Mark (NIH/OD) [E] <[RohrBauM@od.nih.gov](mailto:RohrBauM@od.nih.gov)> wrote:

There is no "list" but we do have a database with CRADA and license information.

**From:** James Love [<mailto:jamespackardlove@gmail.com>]  
**Sent:** Thursday, January 19, 2017 7:01 PM  
**To:** Kassilke, Deborah (NIH/OD) [E] <[deborah.kassilke@nih.gov](mailto:deborah.kassilke@nih.gov)>  
**Cc:** [claire.cassedy@keionline.org](mailto:claire.cassedy@keionline.org); Rohrbaugh, Mark (NIH/OD) [E] <[RohrBauM@OD.NIH.GOV](mailto:RohrBauM@OD.NIH.GOV)>  
**Subject:** Re: Your requests for information from NIH OTT

These are the types of data that make it hard to believe you don't have registry or list of the CRADAs.

<https://www.ott.nih.gov/tt-metrics/crada-metrics>

On Fri, Jan 20, 2017 at 12:56 AM, James Love <[jamespackardlove@gmail.com](mailto:jamespackardlove@gmail.com)> wrote:

Thank you.

We do note that the NIH is able to report the total number of CRADAs in any given year, and also that that number is quite a bit smaller than the number of CRADAs noticed in the federal register.

For number of CRADAs, <https://www.ott.nih.gov/ott-statistics>

We are mostly interested in the Standard CRADAs.

We thought if the NIH could provide a count of the number of CRADAs, they must have a registry or list or database that lists the CRADAs, with the name of the CRADA partner and the purpose of the CRADA.

We were surprised when we were told that no such lists exist.

The CRADAs mentioned in the annual reports do not seem inclusive of all CRADAs in a given year.

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For example:

In FY15, NIH Institutes executed 5,826 of these collaboration and transfer agreements, including 101 new Cooperative Research and Development Agreements (CRADAs).

I don't think there are 101 CRADAs listed in the annual report, or even the 73 for Standard CRADAs.

So, while the Annual report is useful and interesting, we still don't know who is getting the standard CRADAs.

Also, does the NIH issue exclusive licenses under the CRADAs that are not noticed in the federal register? We were told that the NIH practice was to not provide public notice and comment on all CRADAs and that public notice and comment is not available for all exclusive licenses from CRADAs.

Jamie

On Fri, Jan 20, 2017 at 12:26 AM, Kassilke, Deborah (NIH/OD) [E] <[deborah.kassilke@nih.gov](mailto:deborah.kassilke@nih.gov)> wrote:

Mr. Love –

Recently your office contact me and two other employees in my office with questions concerning royalty payments, the use of the Federal Registry in tracking NIH CRADAs, and a request for information on the process by which the NIH enters into a CRADA with an industry collaborator. I am aware that Mark Rohrbaugh (cc'd) spoke directly with Claire Cassidy to discuss many of the CRADA related process components including the use of

Federal Register notices and how IP is addressed in a CRADA. If you still have questions regarding the use of CRADAs at NIH, we can certainly schedule another call with you.

I confirmed that the NIH FOIA office is still working on a FOIA request for you concerning royalty payment information. They apologize for the delay, but the FOIA office is short staffed at this time and they are working diligently to hire and train new staff. We just last week brought in an Acting Director for the FOIA office, Katherine Uhl, who is on detail to us from the FDA. She is working diligently to keep the plates spinning and asked that I relay to you they are working on the request. Ms. Uhl invites you to contact her office for a status of your FOIA request if you so desire; that number is 301-496-5633.

I hope that you are aware that our annual reports and statistics can be found on our website in the "MEDIA Room" tab; they may be helpful to you.

Please let me know if you would like another call scheduled with Mark and me; we will gladly set something up.  
Deb

*Deborah Kassilke  
Director, Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard, Suite 325  
Rockville, MD 20852  
E-Mail:*

*[Deborah.Kassilke@nih.gov](mailto:Deborah.Kassilke@nih.gov)  
Phone: 301-435-5294  
Cell: **b6***

<image001.png>

REL0000023972

**From:** Claire Cassedy [mailto:[claire.cassedy@keionline.org](mailto:claire.cassedy@keionline.org)]  
**Sent:** Tuesday, August 15, 2017 11:38 AM  
**To:** NIH FOIA <[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov)>  
**Subject:** Request FOIA Request Re: CRADAs Executed 2010-2017

Dear FOIA Officer,

Please find attached a Freedom of Information Act request from Knowledge Ecology International regarding Cooperative Research and Development Agreements executed by the NIH from 2010 to 2017. Thank you in advance for your attention to this request.

Sincerely,  
Claire Cassedy

----- Forwarded message -----

**From:** Shmilovich, Michael (NIH/NHLBI) [E] <[michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov)>  
**Date:** Fri, Aug 18, 2017 at 10:34 AM  
**Subject:** FW: miRecule CRADA  
**To:** "jamespackardlove@gmail.com" <[jamespackardlove@gmail.com](mailto:jamespackardlove@gmail.com)>  
**Cc:** "Deutch, Alan (NIH/NHLBI) [E]" <[deutch@nhlbi.nih.gov](mailto:deutch@nhlbi.nih.gov)>, "Bailey, Brian (NIH/NHLBI) [E]" <[bbailey@nhlbi.nih.gov](mailto:bbailey@nhlbi.nih.gov)>

Jamie – All scientific, business and financial information pertaining to the CRADA between MiRecule and NIDCD other than what has already been made public by either by publication, published patent applications or other public disclosures, is strictly confidential. As such, we cannot provide you with a copy of that agreement.

Regards,

Michael A. Shmilovich, Esq., CLP

-----  
22 August 2017  
James Packard Love  
Knowledge Ecology International  
1621 Connecticut Avenue, Suite 500  
Washington, DC 20009  
<http://keionline.org>  
Work: +1.202.332.2670; Mobile: +1.202.361.3040  
[james.love@keionline.org](mailto:james.love@keionline.org)  
IN RE: 82 Fed. Reg. 36809 (August 7, 2017), "Prospective Grant of Exclusive Patent License: MicroRNA  
therapeutics for treating squamous cell carcinomas" to miRecule, Inc.  
Dear Mr. Love:

....

REL0000023972

Dr. Saleh will have direct participation in the research under his company's Cooperative Research and Development Agreement (CRADA) with the National Institute on Deafness and Other Communication Disorders (NIDCD) in order to advance the technology since a positive research outcome under the CRADA is one step closer to the development of a successful therapeutic to at least one squamous cell carcinoma. With respect to your request for various reports including CRADA documents, it is not consistent with our mission to create reports requested by the public and the proprietary content of the agreement governing the CRADA between the NIDCD is strictly confidential. In summary, the CRADA research plan sets forth a joint effort between miRecule and NIDCD to develop chemically modified mimic or mimetic microRNAs that are stable and less susceptible to nuclease degradation than previously identified microRNAs and that serve as therapeutics for cancer when delivered using tumor targeted nanoparticles. The CRADA will test these microRNAs in animal cancer models to evaluate their efficacy and the pharmaceutical properties of candidate formulations.

If your organization requests more documentation, such requests should be filed under the Freedom of Information Act. The webpage for the NIH FOIA Office provides more information on filing requests <http://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedominformation-act-office/submitting-foia-requests>.

Michael A. Shmilovich, Esq., CLP

--

James Love. Knowledge Ecology International

<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,

[twitter.com/jamie\\_love](https://twitter.com/jamie_love)



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**From:** Lambert, Richard (NIH/NIAID) [C] [/O=NIH/OU=NIH/EXCHANGE/CN=NIAID/CN=LAMBERTR]  
**Sent:** 6/5/2017 6:05:16 PM  
**To:** Rohrbach, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/cn=OD/cn=ROHRBAUM]  
**Subject:** FW: [Ip-health] Eight Takeaways from the Army/Sanofi/Zika License Fiasco

Hi Mark. An FYI  
Dick

Richard A. Lambert  
Contractor  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health  
U.S. Department of Health and Human Services  
5601 Fishers Lane, Rm. 2G47, MSC 9804  
Bethesda, MD 20892-9804  
(Courier: Rockville, MD. 20852)  
301.496.2644 main officeline  
240.627.3706 direct line  
FAX 240.627.3117  
lambertr@niaid.nih.gov

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-----Original Message-----

**From:** Claire Cassedy [mailto:claire.cassedy@keionline.org]  
**Sent:** Monday, June 05, 2017 1:17 PM  
**To:** ip-health@lists.keionline.org  
**Subject:** [Ip-health] Eight Takeaways from the Army/Sanofi/Zika License Fiasco

[https://medium.com/@jamie\\_love/a-couple-of-takeaways-from-the-army-sanofi-zika-license-fiasco-e441f0e427dd](https://medium.com/@jamie_love/a-couple-of-takeaways-from-the-army-sanofi-zika-license-fiasco-e441f0e427dd)

Eight Takeaways from the Army/Sanofi/Zika License Fiasco

James Love - 4 June 2017

For those of you following the efforts by the US Army to license a patent on a vaccine for the Zika vaccine, to Sanofi, the French drug and vaccine manufacturer, here is a quick summary of the facts, and a few takeaways.  
The facts.

1. The US Army invented in the vaccine in the spring of 2016, applied for a patent, and shortly thereafter, proposed licensing the patent on an exclusive basis to Sanofi, a giant French drug company.
2. The US government is financing and conducting a Phase 1 clinical trial, right now.
3. The US government is paying Sanofi \$43 million to conduct a Phase 2 trial of the vaccine.
4. The US government will pay Sanofi another \$130 million pay for the Phase 3 trial.
5. Sanofi describes its contribution as a willingness to do the Phase 2 and 3 trials (at US government expense) instead of having its workers do something even more profitable, as if Sanofi can only work on one vaccine at a time.
6. The US Army has rejected the suggestion they wait to license the patents until data from the any of the Army/NIH/BARDA financed Phase 1-3 trials are in, even though that would only make the government's leverage stronger, if the results are positive.
7. Sanofi has been cited four times since 2009 for cheating Medicaid, veterans and US consumers, and faces criminal charges in France and Germany for kickbacks and fraud. The most recent US case was April 3, 2017, and involved a \$20 million fine for overcharging the U.S. Department of Veterans Affairs (<https://www.justice.gov/opa/pr/sanofi-pasteur-agrees-pay-198-million-resolve-drug-overcharges-department-veterans-affairs>). (link here: <http://keionline.org/sanofi-fines>)
8. Sanofi has a history of charging US residents more. For example, the

price for its multiple sclerosis drug Aubagio (teriflunomide) is more than \$6,000 \*per month \*in the United States (\$5,276 for Medicare in 2015), and about \$750 per month in France. (more here: <http://keionline.org/node/2759>)

9. According to MSF, Sanofi has a track record of charging high prices for vaccines in developing countries.

10. The largest share of U.S. cases of the Zika virus are in Puerto Rico, where many of the persons who need to be vaccinated are on Medicaid.

11. The US Army asked Sanofi if they were willing to make a binding commitment to not charge US residents more than the price charged in other high income industrialized countries. Sanofi said — no. Sanofi wants the freedom to charge whatever they want in the US market. (who can blame Sanofi, at least they at least know what's best for their shareholders.)

#### The takeaways

1. The notion that you can solve drug pricing problems by subsidizing clinical trials (a "new idea" floated every couple of years) is flawed, if you don't connect the public sector investments to the product pricing.
2. Complaining about high prices is more popular with politicians than doing something about it.
3. The Army's unwillingness to deal with what is obviously a bad deal for the US taxpayers and consumers is largely a resistance to creating a precedent. The Army, like the NIH, does not want to ever be asked to consider the costs of the monopoly on the public, or negotiate shorter monopoly terms and/or conditions on pricing. The Zika license is a threat to this tranquillity.
4. Agencies that end up paying for drugs and vaccines don't weigh-in on licensing decisions. This is surprising, given how much money exclusive licenses end up costing Medicare, Medicaid, the Department of Veterans Affairs and federal employees.
5. OMB does not reflect on the future budget impact of exclusive licenses.
6. Lately, the only members of Congress who have shown an interest in the absurdity of paying for the R&D, without getting any conditions on pricing, are democrats, a partisan split which makes the reforms quite difficult.
7. The smart move here is for the Army to at least delay signing a bad contract, until the government has results from the Phase 2 trial, it has ALREADY FUNDED. Doing nothing for now does not preclude an exclusive license later, but even that is hard to accomplish.
8. Sanofi and the Army both have managed to tell Congress and the public the minimum about the proposed license, even when the details are fairly routine. Why? Because a bad deal is more defensible when the Army can dismiss its critics as uninformed.

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Ip-health mailing list

[Ip-health@lists.keionline.org](mailto:Ip-health@lists.keionline.org)

[http://lists.keionline.org/mailman/listinfo/ip-health\\_lists.keionline.org](http://lists.keionline.org/mailman/listinfo/ip-health_lists.keionline.org)

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**From:** Rodriguez, Richard (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8092CB5394E04733AC0D4D84D25F65E5-RODRIGR]  
**Sent:** 11/7/2017 8:37:21 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: responses to FRNs

We've worked with you to provide general answers that are only responsive to the intent to grant notice. Overall, I thought [REDACTED] **b5**

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Tuesday, November 7, 2017 2:35 PM  
**To:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
**Subject:** RE: responses to FRNs

Does the TLM answer the questions to the extent the answer does not reveal confidential information?

**From:** Rodriguez, Richard (NIH/NCI) [E]  
**Sent:** Tuesday, November 07, 2017 1:13 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Subject:** RE: responses to FRNs

Hi again,

A pretty quick response from NCI staff. KEI and Sara Elizabeth Siegler routinely ask these types of questions. I can provide examples if you like, so please let me know.

Richard

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Tuesday, November 7, 2017 10:39 AM  
**To:** Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
**Subject:** responses to FRNs

Richard:

Do you recall our receiving questions from a FRN notice not directly related to the technology and the license, such as how much money was spent in developing this technology, or did this company receive government funding?

How was this handled or how are you handling it now?

Thx

Mark L. Rohrbaugh, Ph.D., J.D.  
Special Advisor for Technology Transfer  
Director, Division of Technology Transfer and Innovation Policy  
Office of Science Policy  
Office of the Director

REL0000023977



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**From:** Lambert, Richard (NIH/NIAID) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9668E9326D084AC893665B084FDFD4FE-LAMBERTR]  
**Sent:** 4/18/2019 11:32:32 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** Fwd: [Ip-health] Washington Post on NIST Bayh-Dole proposals: A rare deterrent to limitless drug price increases may die under Trump

Fyi

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**From:** "James Love" <[james.love@keionline.org](mailto:james.love@keionline.org)>  
**Date:** Thursday, April 18, 2019 at 4:26:29 PM  
**To:** "Ip-health" <[ip-health@lists.keionline.org](mailto:ip-health@lists.keionline.org)>  
**Subject:** Re: [Ip-health] Washington Post on NIST Bayh-Dole proposals: A rare deterrent to limitless drug price increases may die under Trump

I will add a few points to the Washington Post article:

Bayh was not only a lobbyist after leaving the government, he represented CellPro in 1997, where he argued that licensing practices that lead to higher prices on consumers were a reason to issue a march-in:

"investigation may be needed to determine whether the royalty layering that plainly exists in the present case . . . is a common problem that leads to unreasonably high royalties (and prices of medical care) that should be dealt with by regulation." (See: <https://www.keionline.org/21970>)

Later Bayh was employed by a firm that represented Abbott, during the 2004 ritonavir case, and by then, he switched his views, to say that "available to the public on reasonable terms" have nothing to do with prices to the public.

The notion that march-in rights 'have never been used' is partly right, but partly wrong. In several cases where march-in rights have been raised, the government has extracted some concessions on patent holders. Several such was noted here: <https://www.keionline.org/cl/march-in-royalty-free>

There are currently a few cases where the federal government is currently being asked to use march-in rights, including the PreP4All campaign, as well as a new Xtandi/enzalutamide case, that was brought to test the Senator Armed Services Committee 2017 directive on march-in rights in the National Defense Authorization Act, and there are other cases that may be filed in the near term, including one on Spinraza/Nusinersen, plus others.

NIST's director, Undersecretary of Commerce Walter G. Copan is probably the main reason the march-in and royalty free rights are under attack.

<https://www.nist.gov/people/walter-g-copan>  
<https://www.linkedin.com/in/waltercopan/>

REL0000023978

On Thu, Apr 18, 2019 at 3:44 PM James Love <james.love@keionline.org> wrote:

>  
>  
> [https://www.washingtonpost.com/business/economy/a-rare-deterrent-to-limitless-drug-price-increases-may-die-under-trump/2019/04/17/7578e5e0-5bcd-11e9-a00e-050dc7b82693\\_story.html?utm\\_term=.631439137a8b](https://www.washingtonpost.com/business/economy/a-rare-deterrent-to-limitless-drug-price-increases-may-die-under-trump/2019/04/17/7578e5e0-5bcd-11e9-a00e-050dc7b82693_story.html?utm_term=.631439137a8b)  
>  
> A rare deterrent to limitless drug price increases may die under Trump  
>  
> Sen. Birch Bayh (D-Ind.), left, and Sen. Bob Dole (R-Kan.) meet in  
> February 1978 at the Capitol during a break in a closed session of the  
> Senate. (John Duricka/Associated Press)  
> By Christopher Rowland April 18  
>  
> As drug prices have soared, lawmakers and patient advocates have pushed  
> the federal government to deploy for the first time a powerful deterrent: a  
> legal provision that allows it to suspend a drugmaker's patent and license  
> someone else to produce the drug.  
>  
> Now, responding to industry alarm over those demands, the Trump  
> administration is proposing to strictly limit the little-known power.  
>  
> The move by the Department of Commerce is supported by drug manufacturers  
> and research universities but could undermine Trump's populist message of  
> attacking drug prices. He declared in his first news conference after his  
> inauguration that drug companies are "getting away with murder" and has  
> called lowering prices one of his "greatest priorities."  
>  
> [An HIV treatment cost taxpayers millions. The government patented it. But  
> a pharma giant is making billions.]  
>  
> Critics say the Commerce Department move is a triumph for industry.  
>  
> "If tough talk and tweets could stop price gouging, consumers could  
> celebrate," said Rep. Lloyd Doggett (D-Tex.), who said the administration  
> is being swayed by drug company influence.  
>  
> The Commerce draft plan would prohibit the government from suspending a  
> drugmaker's exclusive patent over excessive pricing. It targets an obscure  
> provision of a 40-year-old law called Bayh-Dole that is supposed to protect  
> taxpayer interests in government-funded inventions, such as drugs  
> discovered using federal grant money.  
>  
> The law gives the government "march-in rights" to circumvent a patent  
> (and license someone else to market a drug) if the original therapy is not  
> made available to the public "on reasonable terms." But the phrase  
> "reasonable terms" is not defined in the law and for years has been the  
> subject of competing interpretations.  
>  
> The Trump administration plan, which was published as a "summary of  
> intended actions" in December but received little attention, would come

> down clearly in favor of drug companies and major research universities.

>

> March-in rights have never been used by the government, which historically

> has encouraged the flow of discoveries to private business for development.

> The National Institutes of Health, the leading drug research agency, has

> declined multiple times to use march-in rights to control prices —

> including under Democratic President Barack Obama.

>

> But in today’s hyper-charged debates over the costs of U.S. prescription

> drugs, especially with the advent of biotechnology and gene therapies that

> cost hundreds of thousands of dollars a year, the government’s powers are

> getting a closer look.

>

> Consumer advocates argue that the threat of government action is one of

> the few checks on drug prices and could give drug companies second thoughts

> about gouging consumers on drugs that were invented with public funding.

>

> “The pharmaceutical manufacturer takes taxpayers’ money that was invested,

> and takes the government monopoly that is granted, and charges monopoly

> prices without any countervailing force,” Doggett, the chairman of the

> House Ways and Means subcommittee on health, said in an interview.

>

> Constituents in his Texas district, he said, “think they are getting

> ripped off by the same company that used their tax money.”

>

> Doggett led 50 Democrats who wrote to Trump in 2017 urging the president

> to order NIH to create guidelines on when excessive pricing would trigger

> government action. The letter cited Trump’s own declaration after his 2017

> inauguration that drug companies were on the White House target list.

>

> Research universities, where federally sponsored research is conducted,

> have pushed the Trump administration to head off these initiatives.

> Universities reap millions of dollars a year from royalties on inventions

> they license to private companies.

>

> The industry and academic institutions argue that march-in rights, or even

> the threat of march-in rights, raise the specter of price controls and will

> discourage private investors from backing new discoveries.

>

> “If there is a trap door that makes that intellectual property useless,

> and there is a fear that might occur, then you can imagine a company is not

> going to invest the funds necessary to bring the invention to market,”

> said Stephen J. Susalka, chief executive of the AUTM, which advocates for

> research institutions over patents and licensing.

>

> They have found a friendly audience in Trump’s Department of Commerce,

> where the president’s populist political rhetoric is colliding with his

> equally strong desire for industry-friendly deregulation.

>

> The department’s National Institute of Standards and Technology (NIST) is

> scheduled to issue a final draft this month of its proposal, which it is

> calling a “discussion document.” The draft plan would block any government

> agency from exercising march-in rights based on the price of a product.

> Exclusivity rights could still be suspended in times of national emergency

> — such as an epidemic.

>

> NIST's director, Undersecretary of Commerce Walter G. Copan, is a Trump  
> appointee and a longtime expert in the transfer of technology from  
> government-sponsored labs to the private sector. He was unavailable for  
> comment for this article, pending the release of a final document, expected  
> later this month. The final framework will serve as a starting point for  
> drafting new regulations, a process that would take months.

>

> March-in rights "are unfortunately not well defined in current  
> legislation, [which] has led to ambiguities and the attempts to use  
> march-in rights as price control mechanisms," Copan said at a public  
> hearing last year. Holding back prices, he said, "was not the intent at all  
> of the authors" of the law.

>

> The White House Office of Science and Technology Policy echoed that view.  
> "Clear, uniform standards for applying patent march-in rights across the  
> government would benefit the entire innovation ecosystem," a spokesman  
> said Thursday.

>

> Industry and university officials who support NIST's approach say march-in  
> rights were never intended to be used for pricing. The proposal has also  
> galvanized fervent property rights activists such as Andrew Schlafly, son  
> of the late conservative activist Phyllis Schlafly.

>

> "March-in must never be twisted into a means of enacting price controls,"  
> Schlafly wrote in public comments to the government.

>

> But plenty of patent experts disagree that the law's "reasonable terms"  
> should be narrowly applied.

>

> "We have march-in rights for a reason, as a safety valve, and pricing is  
> one of just many issues that could make something not reasonably  
> available," said John R. Thomas, a professor at Georgetown Law who  
> specializes in intellectual property and, as a visiting scholar, wrote a  
> Congressional Research Service report on the subject. "The idea that the  
> price is too high fits pretty comfortably in the wording of the statute."

>

>

> Consumer and social justice organizations, including the nonprofit  
> Knowledge Ecology International, which advocates on patent issues,  
> circulated an open letter to Congress this month warning against the NIST  
> proposals.

>

> A year ago, Trump unveiled a "blueprint" for lowering prescription  
> prices, which included accelerating approvals for generic prescription  
> drugs to provide greater competition. His administration has proposed a  
> rule to eliminate from Medicare Part D all drug company rebates made to  
> pharmacy insurance benefit managers, which are blamed for driving up list  
> prices.

>

> The administration has said it wants to use international comparisons to  
> hold back prices on Medicare drugs delivered in hospitals and doctor's  
> offices. It also wants to require drug companies to include list prices in  
> advertising.

>

> The 1980 Bayh-Dole law is named for its Senate sponsors, Democrat Birch  
> Bayh of Indiana and Republican Bob Dole of Kansas. It set up a framework



> for the modern system that allows federally funded research institutions to  
> license discoveries.  
>  
> Dole and Bayh wrote an op-ed in The Washington Post in 2002 that said  
> controlling prices was never their intent. Advocates, however, have been  
> quick to note that Dole and Bayh were no longer senators when they wrote  
> that article. Dole, who left the Senate in 1996 during his campaign for  
> president, became a Pfizer TV pitch man for Viagra in 1998; Bayh, who died  
> this year, represented the Washington interests of numerous corporate  
> clients after he left the Senate in 1981. In 2002, he was a registered  
> lobbyist for multiple companies.  
>  
> Democratic senators in 2016 asked the Obama administration to exercise  
> march-in rights in response to drug prices and were rebuffed. Obama's  
> Health and Human Services secretary, Sylvia Mathews Burwell, rejected that  
> request, saying that "The statutory criteria are sufficiently clear and  
> additional guidance is not needed."  
>  
> "It was never the intent of Congress to use the Bayh-Dole Act to exercise  
> government price controls," asserted the Pharmaceutical Research and  
> Manufacturers of America, the drug industry lobbying group, in written  
> comments as NIST was drawing up its proposed rules.  
>  
> But Thomas, the Georgetown Law professor, said that analysis is not  
> correct.  
>  
> "Post-enactment legislative history," he said, "isn't really the way the  
> game is played."  
>  
>  
> --  
> James Love. Knowledge Ecology International  
> U.S. Mobile +1.202.361.3040  
> U.S. office phone +1.202.332.2670  
> <http://www.keionline.org> <<http://www.keionline.org/donate.html>>  
> [twitter.com/jamie\\_love](https://twitter.com/jamie_love)  
>

--  
James Love. Knowledge Ecology International  
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<http://www.keionline.org> <<http://www.keionline.org/donate.html>>  
[twitter.com/jamie\\_love](https://twitter.com/jamie_love)

---

Ip-health mailing list  
[Ip-health@lists.keionline.org](mailto:Ip-health@lists.keionline.org)  
[http://lists.keionline.org/mailman/listinfo/ip-health\\_lists.keionline.org](http://lists.keionline.org/mailman/listinfo/ip-health_lists.keionline.org)

**From:** Jorgenson, Lyric (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3BBDE7D361374981A4D336B6EEB17521-JORGENSONLA]  
**Sent:** 7/17/2019 3:34:13 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]  
**CC:** Plude, Denise (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91f83d681d984eaa8fe3de287aebfa01-pludedede]; Ampey, Bryan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9672b522d0b34f3792e2934dac636a57-ampeybc]; Bayha, Ryan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d5a4353cd514322a8598dbb1751ee79-bayhar]  
**Subject:** RE: IMPORTANT FW: WF 384359 - Direct Reply due 7/18  
**Attachments:** WF 384359 Patients for Affordable Drugs.docx

I think that this looks great. I

b5

b5

**From:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Sent:** Tuesday, July 16, 2019 7:03 PM  
**To:** Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>  
**Cc:** Plude, Denise (NIH/OD) [E] <pludedede@mail.nih.gov>; Ampey, Bryan (NIH/OD) [E] <bryan.ampey@nih.gov>; Bayha, Ryan (NIH/OD) [E] <bayhar@od.nih.gov>  
**Subject:** IMPORTANT FW: WF 384359 - Direct Reply due 7/18

b5

They have joined KEI on a few objections to proposed IRP patent licenses but nothing else.

See attached draft response.

b5

**From:** Jorgenson, Lyric (NIH/OD) [E]  
**Sent:** Friday, July 12, 2019 10:53 AM  
**To:** Plude, Denise (NIH/OD) [E] <pludedede@mail.nih.gov>  
**Cc:** Bayha, Ryan (NIH/OD) [E] <bayhar@od.nih.gov>; Ampey, Bryan (NIH/OD) [E] <bryan.ampey@nih.gov>; Koniges, Ursula (NIH/OD) [E] <ursula.koniges@nih.gov>; Fennington, Kelly (NIH/OD) [E] <fenningk@od.nih.gov>; Wertz, Jennifer (NIH/OD) [E] <wertzj@od.nih.gov>  
**Subject:** Re: WF 384359 - Direct Reply due 7/18

b5

Lyric Jorgenson, PhD  
Deputy Director, Office of Science Policy  
National Institutes of Health  
301.496.6837

On Jul 12, 2019, at 7:39 AM, Plude, Denise (NIH/OD) [E] <pludedede@mail.nih.gov> wrote:

b5

**From:** Bayha, Ryan (NIH/OD) [E]  
**Sent:** Tuesday, July 09, 2019 6:40 PM

REL0000023980

**To:** Ampey, Bryan (NIH/OD) [E] <bryan.ampey@nih.gov>; Koniges, Ursula (NIH/OD) [E] <ursula.koniges@nih.gov>; Plude, Denise (NIH/OD) [E] <pludedede@mail.nih.gov>; Fennington, Kelly (NIH/OD) [E] <fenningk@od.nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>  
**Cc:** Wertz, Jennifer (NIH/OD) [E] <wertzi@od.nih.gov>  
**Subject:** RE: WF 384359 - Direct Reply due 7/18

Since this is direct reply,

**b5**

**From:** Ampey, Bryan (NIH/OD) [E] <bryan.ampey@nih.gov>  
**Sent:** Tuesday, July 9, 2019 3:30 PM  
**To:** Koniges, Ursula (NIH/OD) [E] <ursula.koniges@nih.gov>; Plude, Denise (NIH/OD) [E] <pludedede@mail.nih.gov>; Bayha, Ryan (NIH/OD) [E] <bayhar@od.nih.gov>; Fennington, Kelly (NIH/OD) [E] <fenningk@od.nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>  
**Cc:** Wertz, Jennifer (NIH/OD) [E] <wertzi@od.nih.gov>  
**Subject:** RE: WF 384359 - Direct Reply due 7/18

Mark passed this along earlier too for awareness. This is the same group requesting a direct reply

Here is the link: <https://www.statnews.com/2019/07/09/dc-diagnosis-drug-prices-tv-ads/>

## Drug pricing advocates put NIH in the hot seat

The drug industry foe Patients For Affordable Drugs has a new report out this morning arguing that taxpayers have contributed at least \$300 million toward the development of a gene therapy to cure sickle cell disease — and the group says that's reason enough for the NIH to demand the treatment be reasonably priced.

“Given the \$1 to \$2 million price range of recent gene therapies, we are concerned that a sickle cell cure will be brought to market at a price that is unaffordable for patients and for the taxpayers who supported its development,” the group writes. “The NIH should use all levers in its power to ensure the final price accounts for public investment.”

The group has a number of suggestions to NIH on how to establish pricing guardrails, including requiring that the drug maker price the drug at no more than the average of comparable OECD nations.

This isn't the first time drug pricing advocates have railed against NIH licensing out government-developed drugs without restricting what drug makers can charge, but those complaints so far have fallen on deaf ears.

An NIH spokesperson declined to comment on P4AD's pricing concerns and emphasized that NIH does not have a role in setting prices. The spokesperson also disputed P4AD's argument that \$300 million went to the development of this one particular therapy, because the NIH studies were foundational research studies. “You can't take foundational studies and apply them to one product,” the spokesperson said.

Bryan Ampey, Ph.D.  
Health Science Policy Analyst

REL0000023980

Office of Science Policy, Office of the Director  
National Institutes of Health  
301-451-6346

<image001.png>

**From:** Koniges, Ursula (NIH/OD) [E]  
**Sent:** Tuesday, July 09, 2019 3:27 PM  
**To:** Plude, Denise (NIH/OD) [E] <pludedede@mail.nih.gov>; Ampey, Bryan (NIH/OD) [E] <bryan.ampey@nih.gov>; Bayha, Ryan (NIH/OD) [E] <bayhar@od.nih.gov>; Fennington, Kelly (NIH/OD) [E] <fenningk@od.nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>  
**Cc:** Wertz, Jennifer (NIH/OD) [E] <wertzj@od.nih.gov>  
**Subject:** RE: WF 384359 - Direct Reply due 7/18

Please assign this to Mark. Thanks Denise!

**From:** Plude, Denise (NIH/OD) [E] <pludedede@mail.nih.gov>  
**Sent:** Tuesday, July 09, 2019 3:26 PM  
**To:** Ampey, Bryan (NIH/OD) [E] <bryan.ampey@nih.gov>; Bayha, Ryan (NIH/OD) [E] <bayhar@od.nih.gov>; Fennington, Kelly (NIH/OD) [E] <fenningk@od.nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Koniges, Ursula (NIH/OD) [E] <ursula.koniges@nih.gov>  
**Cc:** Wertz, Jennifer (NIH/OD) [E] <wertzj@od.nih.gov>  
**Subject:** WF 384359 - Direct Reply due 7/18

### **Work Folder Information**

**Work Folder:** WF 384359

**Process:** Direct Reply

**Program Analyst:** Whitfield, Michelle D. (NIH/OD) [E]

**Due Date:** July 18, 2019

**WF Subject:** Writer urges NIH to review policies under which taxpayer-funded discoveries are licensed to private corporations that then price the drug out of reach for patients and our health system.

**IC:** od\_osp

**From:** Mitchell, David

**To:** Collins, Francis

**Remarks:** Assigned to OSP for direct reply with clearance by 7/18/19. Please prepare a draft response and submit to ES by cob 7/18/19 for clearance. Once the response has been cleared, ES will return to OSP for mailing. Also, if OSP feels this should be a Dir Sig or DepD Sig, please let me know. Thank you.

**b5**

**b5**

**b5**

---

**From:** Lambertson, David (NIH/NCI) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=LAMBERTSOND]  
**Sent:** 8/4/2016 5:49:12 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]  
**Subject:** Language for a Response Letter to an Objection from KEI

Good afternoon Mark,

I am currently preparing a letter to send to KEI as a response to an objection they filed against two Notices of Intent to Grant. With review and assistance from Richard Rodriguez and Dale Berkley, we have the preponderance of the letter put together. However, Dale wanted me to pass our proposed response to a particular matter in the objection by you for review, since it concerns technology transfer policy.

The specific matter is a request by KEI that we include pricing restrictions on products produced under the license. The following is Dale's proposed response:

**b5**

Cheers,  
Dave

David A. Lambertson, Ph.D.  
Senior Licensing and Patenting Manager  
Technology Transfer Center  
National Cancer Institute/NIH  
[david.lambertson@nih.gov](mailto:david.lambertson@nih.gov)  
<http://ttc.nci.nih.gov/>

9609 Medical Center Drive, Rm 1-E530 MSC 9702  
Bethesda, MD 20892-9702 (USPS)  
Rockville, MD 20850-9702 (Overnight/express mail)  
Phone (Main Office): 240-276-5530  
Phone (direct): (240) 276-6467  
Fax: 240-276-5504

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**From:** Dodson, Sara (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=985A956EAA0D4945BDCFD8EA30947D68-DODSONSE]  
**Sent:** 2/12/2018 4:30:20 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Koniges, Ursula (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d5ae2c3139654bc0b9b95718d516310b-konigesum]  
**Subject:** FW: Articles of Note: Monday February 12, 2018  
**Attachments:** Is the Novartis breakthrough gene therapy overpriced or not.docx

Just making sure you both see these 2 commentaries re: the price of Novartis' Kymriah and NIH's investment in CAR-T. See attached for a post from Pharmedica and here for a related blogpost in Health Affairs:

<https://www.healthaffairs.org/doi/10.1377/hblog20180205.292531/full/>

Authors include David Mitchell, who created Patients for Affordable Drugs, and Aaron Kesselheim from Harvard. Both are backed by the Arnold Foundation.

Of note, the \$200M estimate of NIH's investment in CAR-T is discussed. It is also referred to as an analysis done by KEI.

Sara

**From:** Bayha, Ryan (NIH/OD) [E]  
**Sent:** Monday, February 12, 2018 11:07 AM  
**To:** OD-OSP <ODOSP@OD.NIH.GOV>  
**Subject:** Articles of Note: Monday February 12, 2018

Good morning,

Below, please find your Monday roundup.

1. Genetic similarities between dogs and people are helping cancer research

<https://partner.criticalmention.com/app/#/clip/slim/a777ca18-04b8-48d3-9c53-38fa8b94f0ae>

2. Purdue Pharma is promising no longer to promote its opioid drugs with visits to doctor's offices

<https://partner.criticalmention.com/app/#/clip/slim/e6e3c9ff-da65-48f6-acd0-4aace1f0aff4>

3. Trump's 2019 budget plan already outdated after budget deal

<https://apnews.com/cb417c4f3565492f952d8b0f2b5e5134/Trump-budget-plan-already-outdated-after-budget-deal>

4. Milwaukee Health Department chief says "science is still out on vaccine-autism" link; sharp criticism ensues

<https://www.jsonline.com/story/news/2018/02/09/milwaukee-newly-picked-top-health-official-says-science-still-out/323462002/>

5. Is Kymriah overpriced or not? (attached)

**Related:** The high price of Tisagenlecleucel (from Taunton)

<https://www.healthaffairs.org/doi/10.1377/hblog20180205.292531/full/>

6. Lack of Trump Administration leadership exacerbated this year's Flu

<https://www.nytimes.com/2018/02/09/sunday-review/trump-flu-shot.html>

**On this day:**

- In 1789, Revolutionary War hero Ethan Allen dies at age 51 (possibly of sticker shock from knowing the price of an ottoman at his namesake).
- In 1809, 16th president, Abraham Lincoln is born in Hardin County Kentucky.
- In 1809, naturalist Charles Darwin is born in Shrewsbury, Shropshire.
- In 1874, Hawaii King David Kalakaua is 1st king to visit the US as guest of Ulysses S. Grant at 1st US state dinner at the White House
- In 1994, "The Scream" by Norwegian painter Edvard Munch is stolen in Oslo

Thanks

Ryan

**Ryan T. Bayha**  
**Director of Strategic Engagement**  
**National Institutes of Health**  
**Office of Science Policy**  
**6705 Rockledge Drive, Suite 750**  
**Bethesda, MD 20892**  
**301- 496-9838 (p)**  
**301-496-9838 (f)**

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# Is the Novartis breakthrough gene therapy overpriced or not?

By Ed Silverman @Pharmalot

February 9, 2018

Late last year, Novartis (NVS<sup>1</sup>) began marketing a breakthrough gene therapy for treating youngsters with advanced leukemia and slapped a \$475,000 price tag on the one-time treatment. The eye-popping number sparked debate, but the drug was quickly deemed cost effective<sup>2</sup> by a nonprofit watchdog.

The controversy is far from over, though.

A new analysis<sup>3</sup> claims the drug, which is called Kymriah, is way overpriced and could cost one-third less, or \$160,000, while still allowing Novartis to pocket its historic profit margins. And the researchers further argue there is a sad irony — the cost may preclude some patients from receiving access to the drug, even though it was developed with U.S. taxpayer funds.

“Prescription drugs should be priced in a way that maximizes patient access while ensuring adequate compensation for research and development pipelines and healthy incentives for meaningful innovation,” write the authors in *Health Affairs*, a health policy journal.

“Ultimately, the question cannot only be: How will we pay for this drug? We must also ask: How much profit is fair for a drug that could keep people alive, especially one that U.S. taxpayers supported the foundational science to invent?”

“Sorry to be Debbie Downer, but Kymriah is never going to provide a positive ROI, even at \$475,000. Like Sovaldi, this is the opposite of the right example to target as pharma greed.”

Brian Skorney, an analyst at Baird

They calculated Novartis would earn an average annual operating profit of 84 percent over the next 10 years. “After allocating 19 percent of revenue annually for Novartis’s historic reported level of research and development, Novartis would still reap a net profit of 65 percent,” the analysis stated, which is “almost 2.5 times what the company generates on its current product portfolio.”

The drug is only the latest entrant in an ongoing debate over the value of medicines. The same issue arose repeatedly with the groundbreaking hepatitis C treatments sold by Gilead Sciences (GILD<sup>4</sup>), which caused a firestorm when first launching its Sovaldi drug at a cost of \$1,000 a pill, or \$84,000 for a 12-week regimen. That was the list price, but initially, Gilead was extremely skimpy about offering rebates.

In its defense, the company argued its pill would save the health care system from much higher costs that might otherwise be spent on liver transplants, liver cancer, and hospitalizations. This is the same argument offered for a growing number of high-priced medicines, including Kymriah which, by the way, is a CAR-T therapy.

A Novartis spokesman pushed back against estimates that more than \$200 million in research funded by the National Institutes of Health helped develop the CAR-T approach to cancer care. “None of the \$200 million was used to develop the therapy for FDA approval and there was no direct government funding to Novartis,” he wrote us. The company “assumed full financial responsibility” in 2012.

Indeed, another part of the argument is steep investment. Novartis claims it spent \$1 billion to bring the drug to market, although the spokesman tells us the cost of Kymriah manufacturing “has never been made public and cannot be for proprietary reasons.” But he disputed estimates from Dr. Carl June, the principal investigator on the Kymriah trial, who gauged the production cost was \$20,000 per infusion.

“Sorry to be Debbie Downer, but Kymriah is never going to provide a positive ROI [return on investment], even at \$475,000,” Baird analyst Brian Skorney tweeted after the Health Affairs analysis appeared on Thursday. “Like Sovaldi, this is the opposite of the right example to target as pharma greed.”

Indeed, the recent cost-effectiveness analysis by the Institute for Clinical and Economic Review found that, by using the Novartis drug, the cost would exceed standard chemo by almost \$400,000, but provide a child with about eight extra years of life, on average. And all patients could be treated without crossing an affordability threshold tied to U.S. economic growth. ICER calculates a five-year, annualized potential budget impact to be \$915 million per year for new drugs.

The ICER analysis is only a draft, so presumably, could change. But for now, the findings are significant, given that the nonprofit has not shied away from releasing analyses criticizing many other medicines — including the Sovaldi hepatitis C treatment — as overpriced.

---

Top of Form

Bottom of Form

It is also pointing out that Novartis is working with Medicare and private insurers to charge them only for patients who respond after the first month of treatment. These so-called value-based pricing schemes are becoming more popular as drug makers try to ensure reimbursement for their medicines, although the tactic may be most useful for higher-priced therapies.

Nonetheless, the Health Affairs authors suggest creating an advisory committee to assist the agency in negotiating prices to be paid by patients, requiring U.S. patients not to be charged more than the average price in six other wealthy nations, and issuing a formal request for information on approaches the NIH could use to address pricing issues when working with drug makers to develop and commercialize a medicine.

One final note: ICER is funded by the John and Laura Arnold Foundation, which is spending liberally to influence the national discussion on drug pricing. Among others who receiving backing are two of the Health Affair authors — Dr. Aaron Kesselheim, a Harvard Medical School professor, and David Mitchell, who created Patients for Affordable Drugs with support from the foundation.



---

**From:** Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/CN=RECIPIENTS/CN=HAMMERSLAA]  
**Sent:** 6/16/2017 3:02:36 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIH/EXCHANGE/cn=OD/cn=ROHRBAUM]  
**Subject:** RE: Please send a copy of the signed KEI Response

Interesting. Thanks for the update. Ann

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Friday, June 16, 2017 10:52 AM  
**To:** Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>  
**Subject:** Re: Please send a copy of the signed KEI Response

They asked Dale to send any comments today so they can then run it by FC and LT

Sent from my iPhone

On Jun 16, 2017, at 9:54 AM, Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov> wrote:

Thanks much. I am on AL next week and I alerted Michelle that it may be coming through Exec. Sec. Since this issue is open I will take my laptop. I have also alerted Scott Cooper if something is needed to be done. If you need to reach me or alert me that something came through next week you can send me an email at: b6

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Friday, June 16, 2017 9:46 AM  
**To:** Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>  
**Subject:** Re: Please send a copy of the signed KEI Response

I told them you and I worked on it

Sent from my iPhone

On Jun 16, 2017, at 9:37 AM, Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov> wrote:

--

Ann M. Hammersla, J.D.  
Director  
Division of Extramural Inventions and Technology Resources  
Office of Policy for Extramural Research Administration  
Rockledge 1, Suite 310  
6705 Rockledge Drive  
Bethesda, Maryland 20892-7974  
PHONE: 301-435-0745

**From:** Lambertson, David (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C95B34F709746A8A2553CE54E74ACE2-LAMBERTSOND]  
**Sent:** 4/18/2019 9:59:13 AM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**Subject:** RE: Kite/Gilead license

**b5**

David A. Lambertson, Ph.D.  
Senior Technology Transfer Manager  
Technology Transfer Center  
National Cancer Institute/NIH  
david.lambertson@nih.gov  
<http://ttc.nci.nih.gov/>

9609 Medical Center Drive, Rm 1-E530 MSC 9702  
Bethesda, MD 20892-9702 (USPS)  
Rockville, MD 20850-9702 (Overnight/express mail)  
Phone (Main Office): 240-276-5530  
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Fax: 240-276-5504

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-----Original Message-----

From: Rohrbaugh, Mark (NIH/OD) [E]  
Sent: Wednesday, April 17, 2019 3:37 PM  
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>  
Subject: RE: Kite/Gilead license

Dave

I don't have access to TTS today.

**b5**

**b5**

Thanks

-----Original Message-----

From: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>  
Sent: Wednesday, April 17, 2019 12:14 PM  
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
Subject: RE: Kite/Gilead license

I don't recall doing this, sorry.

David A. Lambertson, Ph.D.  
Senior Technology Transfer Manager  
Technology Transfer Center  
National Cancer Institute/NIH  
david.lambertson@nih.gov  
<http://ttc.nci.nih.gov/>

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-----Original Message-----

From: Rohrbaugh, Mark (NIH/OD) [E]  
Sent: Wednesday, April 17, 2019 12:13 PM  
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>  
Subject: RE: Kite/Gilead license

REL0000023988

Hi Dave.

b5

b5

-----Original Message-----

From: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>  
Sent: Wednesday, April 25, 2018 1:50 PM  
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
Subject: RE: Kite/Gilead license

b5

Let me know if I can be of any further assistance.

Dave

David A. Lambertson, Ph.D.  
Senior Technology Transfer Manager  
Technology Transfer Center  
National Cancer Institute/NIH  
david.lambertson@nih.gov  
<http://ttc.nci.nih.gov/>

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-----Original Message-----

From: Rohrbaugh, Mark (NIH/OD) [E]  
Sent: Wednesday, April 25, 2018 1:32 PM  
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>  
Cc: Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
Subject: Re: Kite/Gilead license

Thanks much.

b5

Sent from my iPhone

> On Apr 25, 2018, at 1:20 PM, Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov> wrote:  
>  
> Hi Mark,  
>  
> The subject matter of the lawsuit revolves around E-001-2016-0, a technology concerning anti-CD30 CARs.  
>

REL0000023988



**b5**

> Please let me know if you need additional details.  
>  
> Dave  
>  
> David A. Lambertson, Ph.D.  
> Senior Technology Transfer Manager  
> Technology Transfer Center  
> National Cancer Institute/NIH  
> david.lambertson@nih.gov  
> http://ttc.nci.nih.gov/  
>  
> 9609 Medical Center Drive, Rm 1-E530 MSC 9702 Bethesda, MD 20892-9702  
> (USPS) Rockville, MD 20850-9702 (Overnight/express mail) Phone (Main  
> Office): 240-276-5530 Phone (direct): (240) 276-6467  
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> Note: This email may contain confidential information. If you are not  
> the intended recipient, any disclosure, copying or use of this email  
> or the information enclosed therein is strictly prohibited, and you  
> should notify the sender for return of any attached documents  
>  
> -----Original Message-----  
> From: Rohrbaugh, Mark (NIH/OD) [E]  
> Sent: Wednesday, April 25, 2018 1:10 PM  
> To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>;  
> Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>  
> Subject: Kite/Gilead license  
>  
> Dave:  
>  
> Dr. Tabak got a call from downtown about the lawsuit. I am getting the CAR-T licenses confused. **b5**

**b5**

>  
> Thanks  
> Mark  
>  
> Sent from my iPhone

---

**From:** Pollard, Ricquita (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DC946982E43F43CB925773EA52C40AFA-POLLARDRD]  
**Sent:** 9/5/2018 1:32:07 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]  
**CC:** Chatterjee, Sabarni (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4520fc058d6457aac24b57685235b12-chatterjees]  
**Subject:** FW: Prospective Grant of an Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy, per 83 FR 35665  
**Attachments:** Response to KEI\_comments on A-311-2018\_082018.docx

Hi Mark,

I am following up on the review status of the attached response to KEI. Please let me know if you have any questions or concerns.

Thanks,  
Ricquita

---

**From:** Pollard, Ricquita (NIH/NCI) [E]  
**Sent:** Wednesday, August 29, 2018 5:59 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>  
**Cc:** Chatterjee, Sabarni (NIH/NCI) [E] <sabarni.chatterjee@nih.gov>  
**Subject:** RE: Prospective Grant of an Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy, per 83 FR 35665

Hi Mark,

Attached please find additional details in the response to KEI. If you have time to discuss over the phone, please let me know.

Thanks,  
Ricquita

---

**From:** Rohrbaugh, Mark (NIH/OD) [E]  
**Sent:** Tuesday, August 21, 2018 4:18 PM  
**To:** Pollard, Ricquita (NIH/NCI) [E] <ricquita.pollard@nih.gov>  
**Cc:** Chatterjee, Sabarni (NIH/NCI) [E] <sabarni.chatterjee@nih.gov>  
**Subject:** RE: Prospective Grant of an Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy, per 83 FR 35665

Ricquita: This is a good outline. I would suggest

b5

b5

Mark

---

**From:** Pollard, Ricquita (NIH/NCI) [E]  
**Sent:** Tuesday, August 21, 2018 1:03 PM  
**To:** Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>  
**Cc:** Chatterjee, Sabarni (NIH/NCI) [E] <sabarni.chatterjee@nih.gov>

REL0000024617

**Subject:** FW: Prospective Grant of an Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy, per 83 FR 35665

Hi Mark,

I am processing a Start-Up Exclusive License application (A-311-2018) from Midissia Therapeutics for a cancer immunotherapy. The *Federal Register* Notice for this application (attached) was posted on July 27<sup>th</sup> and the comment period according to the notice ended August 13<sup>th</sup>. I received an email from James Love and Manon Ress on August 13<sup>th</sup> (see below) with comments from Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (UACT) addressing four topics: 1) No discrimination against US residents in pricing, 2) Reduce term of exclusivity when revenues are large, 3) Developing countries, and 4) Transparency.

Please see my proposed response in the attached WORD document. If you have any questions or concerns, please let me know.

Thanks,  
Ricquita

**Ricquita D. Pollard, Ph.D.**

Technology Transfer Manager  
Technology Transfer Center  
National Cancer Institute  
9609 Medical Center Drive, Rm 1-E530  
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[pollardrd@mail.nih.gov](mailto:pollardrd@mail.nih.gov)

<https://ttc.nci.nih.gov/index.php>

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**From:** James Love <[james.love@keionline.org](mailto:james.love@keionline.org)>

**Sent:** Monday, August 13, 2018 11:48 PM

**To:** Pollard, Ricquita (NIH/NCI) [E] <[ricquita.pollard@nih.gov](mailto:ricquita.pollard@nih.gov)>

**Subject:** Prospective Grant of an Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy, per 83 FR 35665

August 13, 2018

Ricquita Pollard, Technology Transfer Manager,  
NCI Technology Transfer Center,  
Via Email: [pollardrd@mail.nih.gov](mailto:pollardrd@mail.nih.gov).

Re: Prospective Grant of an Exclusive Patent License to Midissia Therapeutics for the Development and Commercialization of Cancer Immunotherapy, per 83 FR 35665

Dear Ricquita Pollard:

REL0000024617

The following are comments from Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (UACT), on the proposed exclusive license for patents noticed in the Federal Register for a license to Midissia Therapeutics ("Midissia") located in San Francisco, California.

### 1. No discrimination against US residents in pricing

We ask that the NIH include language in the proposed exclusive license to ensure that the prices in the U.S. for any drug, vaccine, medical device or other health technology using the inventions are not higher than the median price charged in the seven countries with the largest gross domestic product (GDP), that also have a per capita income of at least 50 percent of the United States, as measured by the World Bank Atlas Method.

We consider this a modest request to protect U.S. residents, who paid for the R&D that created the licensed inventions.

### 2. Reduce term of exclusivity when revenues are large

In addition to an external reference pricing test, we propose that the exclusivity of the license in the U.S. should be reduced when the global cumulative sales from products or services using the inventions exceed certain benchmarks.

Given the modest cost of acquiring an NIH patented invention, the amount of money the developer needs in sales to justify additional investments in R&D is reduced, as compared to cases where a company develops or acquires the technology from non government sources.

This request is consistent with the statutory requirements of 35 USC 209, which requires that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application."

One possible implementation of revenue benchmarks is as follows: exclusivity will be reduced by one year for every \$500 million in revenue equivalents, earned after the first \$1 billion, where revenue equivalent is defined as global cumulative sales plus market entry rewards as well as government grants or tax credits, for the product or products using the invention. However, the NIH could choose different benchmarks, so long as the limits on exclusivity address the requirements of 35 USC 209, that the incentive is "not greater than reasonably necessary."

### 3. Developing countries

We are concerned that several NIH funded inventions are not accessible in developing countries, due to prices that are high and not affordable in markets where per capita incomes are significantly lower than the United States. For this reason, we ask the NIH to limit the exclusivity in the license to countries that have per capita incomes that are at least 30 percent of the United States.

We also ask the NIH to reach out to the Medicines Patent Pool (MPP), in order to enter into an agreement that gives the MPP an option to negotiate non-exclusive open licenses for the inventions in developing countries.

### 4. Transparency

The licensee should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We will

note that this is not a request to see a company business plan or license application. We are asking that going forward the company be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 USC 209, that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application." Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to market.

Sincerely,

James Love  
Knowledge Ecology International

Manon Anne Ress  
Union for Affordable Cancer Treatment

--

James Love. Knowledge Ecology International  
<http://www.keionline.org/donate.html>

KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584, [twitter.com/jamie\\_love](https://twitter.com/jamie_love)